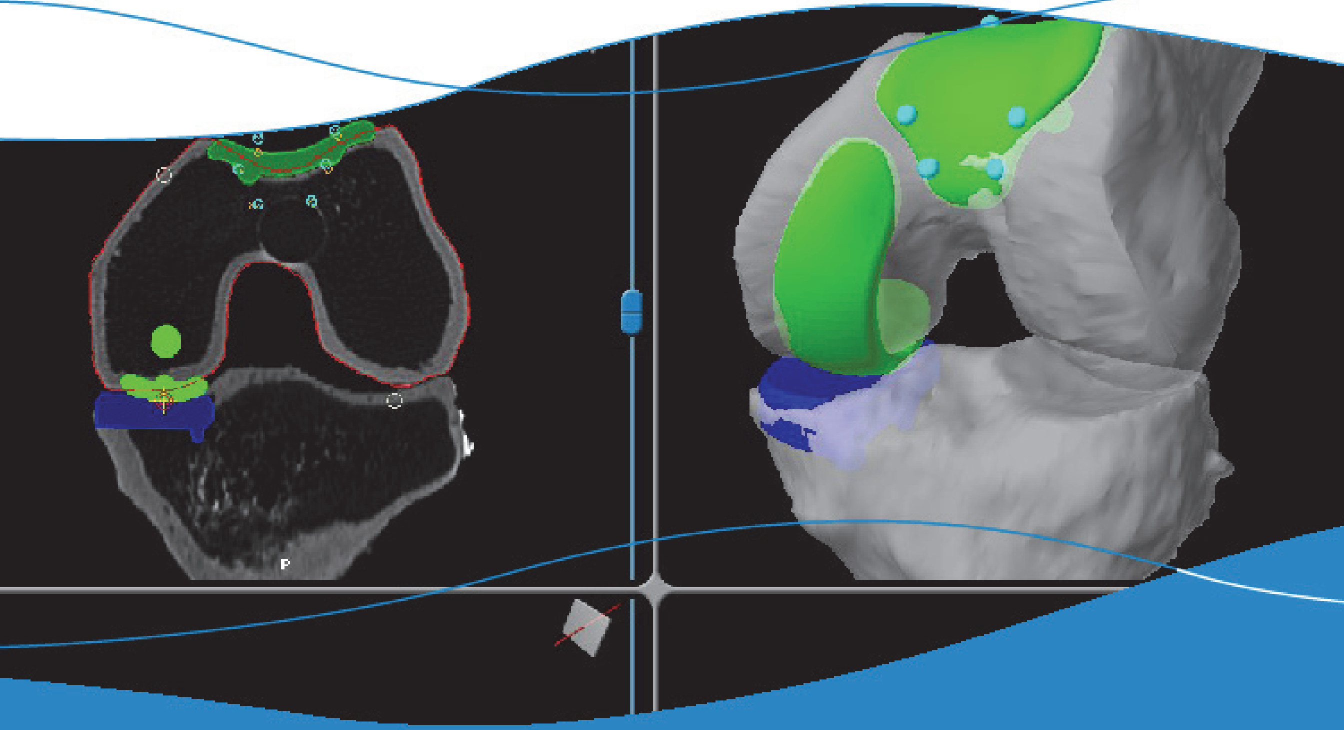
RESTORIS **MCK Planning and Surgical Technique Guide**

206591-15 Rev 00



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INTRODUCTION

RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.

User Manual Terms of Use

This manual is provided by MAKO Surgical Corp. ('MAKO') and may be used for informational purposes only. Terms and Conditions related to the use of the Robotic Arm Interactive Orthopedic System (RIO) can be found in the MAKOplasty agreement with the system user.

About This Manual

This manual describes design considerations, patient selection, implant planning and surgical techniques for implantation of the RESTORIS MCK implant system using both manual instrumentation and assisted by the Robotic Arm Interactive Orthopedic System (RIO). The latter procedure will be identified as MAKOplasty in this manual.

Manufacturer Support/Feedback

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Medical and Product Information

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Indications for Use-RESTORIS PKA

The RESTORIS Partial Knee Application (PKA) for use with the Robotic Arm Interactive Orthopedic System (RIO) is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The RESTORIS Partial Knee Application (PKA) for use with the Robotic Arm Interactive Orthopedic System (RIO) is indicated for use in surgical knee procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT based model of the anatomy. These procedures include unicondylar knee replacement and/or patellofemoral knee replacement.

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Governing Law

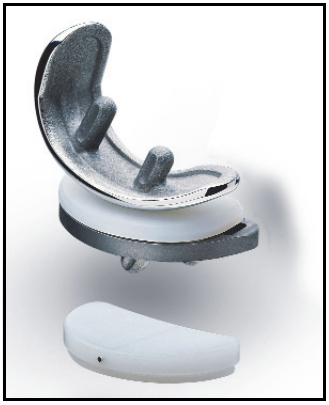
Any legal action or proceeding related to this manual or the information contained in it shall be brought exclusively in a court in Broward County, Florida, and shall be governed by the laws of the State of Florida, without regard to conflicts of laws principles.

Software Version 2.5

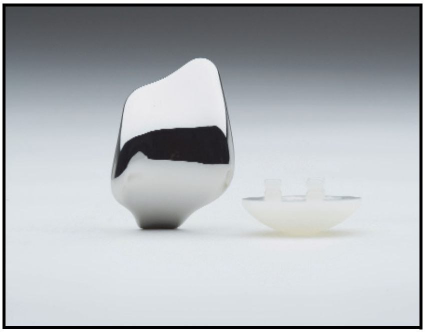
⚠ *There are no user serviceable parts in the RIO, refer to your MAKO authorized personnel for service.*

DESCRIPTION

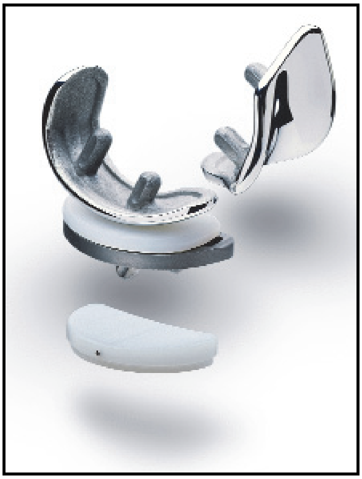
The RESTORIS MCK (MultiCompartmental Knee) Implant System consists of two subsystems: RESTORIS MCK Unicondylar (Uni) which has an inlay* and onlay option, and RESTORIS MCK Patellofemoral (PF). These two subsystems may be used independently or together in a medial multicompartmental implant system referred to in this manual as the MCK Bicompartmental Inlay* or MCK Bicompartmental Onlay. See the end of this manual for technical data of all implants.



Medial or Lateral Unicondylar Inlay or Onlay*



Patellofemoral



Medial Bicompartmental Inlay or Onlay*
(Patella Dome not pictured)
Figure 1. RESTORIS MCK Configuration

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

INDICATIONS FOR USE

RESTORIS MCK Uni

RESTORIS MCK Uni components are for use in unicompartmental knee arthroplasty as a result of: moderately disabling joint disease of the knee resulting from painful osteo- or post-traumatic arthritis, revision of previous unsuccessful unicompartmental knee replacement or as an alternative to tibial osteotomy in patients with unicompartmental osteoarthritis. These components are single use only and are intended for implantation with bone cement.

The indication above regarding the use of RESTORIS MCK Uni for revision of previous unsuccessful unicompartmental knee replacement is not approved in the EU.

RESTORIS MCK PF

RESTORIS MCK PF is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists. These components are single use only and are intended for implantation with bone cement.

RESTORIS MCK Bicompartmental

RESTORIS MCK Bicompartmental is indicated for single or multicompartmental knee replacement used in conjunction with the RIO, Robotic Arm Interactive Orthopedic System, in individuals with osteoarthritis or post-traumatic arthritis of the tibiofemoral and/or patellofemoral articular surfaces.

The specific knee replacement configurations include:

- Medial unicondylar
- Lateral unicondylar
- Patellofemoral
- Medial bi-compartmental (medial unicondylar and patellofemoral)

RESTORIS MCK is for single use only and is intended for implantation with bone cement.

CONTRAINDICATIONS

RESTORIS MCK Uni and RESTORIS MCK PF

RESTORIS MCK (Uni or PF) is contraindicated in patients:

- with greater than 10° of hyperextension, greater than 10° of varus or valgus deformity (Unicondylar only)
- with active infection
- with either mental or neuromuscular disorders that do not allow control of the knee joint
- whose weight, age or activity level might cause extreme loads and early failure of the system
- without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis
- without sufficient soft tissue integrity to provide adequate stability

RESTORIS MCK Bicompartmental

The use of RESTORIS MCK Uni and RESTORIS MCK PF simultaneously for multi compartmental knee replacement is contraindicated in patients:

- with greater than 10° of hyperextension, greater than 10° of varus or valgus deformity
- with active, local infection or previous intra-articular infection
- with neuropathic (Charcot) joint
- with cruciate and collateral ligament insufficiency
- with skeletal immaturity
- with either mental or neurologic conditions that do not allow control of the knee joint or that tend to preempt the patient’s ability or willingness to restrict activities
- without sufficient soft tissue integrity to provide adequate stability
- without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis
- whose weight, age or activity level might cause extreme loads and early failure of the system

PATIENT SELECTION

Selection of multicompartmental knee replacement depends on the judgment of the surgeon with regard to the requirements of the patient. The surgeon should become thoroughly familiar with the technique of implantation for multicompartmental knee surgery by 1) appropriate reading of the literature, and 2) training in the operative skills and techniques required for multicompartmental knee replacement surgery.

The operative surgeon has final decision authority in choosing recipients of the MAKOplasty procedure. The effectiveness of all knee implants can be reduced by poor patient selection.

Additional Patient Selection Guidelines/Considerations

- Articulation of the hip joint is necessary to complete bone registration
- Metal in the operative or non-operative leg can lead to the creation of accuracy-reducing artifacts in the CT scan which can adversely affect the operative plan
- The presence of infection (including history of infection), acute or chronic, local or systemic must be considered
- Insufficient bone quality may affect the stability of the implant
- Patient size may complicate the resection procedure. Body Mass Index should be considered
- Loss of ligament structures may prevent creation of an ideal intra-operative plan
- The significance of the deformity (Hyperextension, Flexion Contracture or Varus/Valgus) must be considered
- Patients with inflammatory arthritis or tricompartmental disease are not candidates for the procedure

WARNINGS AND PRECAUTIONS

Familiarity with and attention to appropriate surgical technique for unicondylar, patellofemoral, multicompartmental arthroplasty, and RESTORIS MCK is essential for success of the procedure.

Only surgeons who have reviewed the literature regarding unicondylar and multicompartmental knee replacement and have had training in the technique using RIO should perform this procedure.

The surgeon or his designee should instruct patients in the limitations of multicompartmental knee replacement, and these patients should be taught to govern their activities accordingly.

Implants and trial components from different manufacturers or implant systems should never be used together since articular and dimensional compatibility cannot be assured.

The use of the RESTORIS MCK Implant system in any configuration requires the use of the Robotic Arm Interactive Orthopedic System (RIO). For more details on RIO driven implementation, see the RIO System User Guide (PN 203857-15)and MAKOplasty Partial Knee Application User Guide (PN 206388-15).

⚠ *RESTORIS MCK is not for lateral bicompartmental patellofemorotibial replacement or for tricompartmental knee replacement.*

Adverse Effects

As with any knee system, potential adverse effects include infection, loosening of the components, breakage or bending of the components, or change in position of the components. There have been reports of sensitivity reactions to the components of knee replacement systems. Other potential adverse effects of knee surgery include neurovascular damage, dislocation, thromboembolic disease, and other less common adverse effects.

Implant Packaging/Sterilization

If any seals or packages are breached, then the component should not be used.

A minimum of 2.5 megarads of gamma irradiation is used for all RESTORIS MCK components. The UHMWPE components are subjected to gamma sterilization and packaged in an inert gas environment.

IMPLEMENTATION USING RIO

RESTORIS MCK Procedure Options

1. **RESTORIS MCK Uni Inlay* (Medial or Lateral)**
   - Femoral Condyle*
   - Tibial Inlay*
2. **RESTORIS MCK Uni Onlay (Medial or Lateral)**
   - Femoral Condyle
   - Tibial Baseplate
   - Tibial Onlay Insert
3. **RESTORIS MCK PF**
   - Patellofemoral (Trochlear) component
   - Patella component
4. **RESTORIS MCK Bicompartmental Inlay* (Medial only)**
   - RESTORIS MCK PF + MCK Uni Inlay*
5. **RESTORIS MCK Bicompartmental Onlay (Medial only)**
   - RESTORIS MCK PF + MCK Uni Onlay

Sizes

All sizes are outlined in the RESTORIS MCK Implant Technical Data section of this manual.

INSTRUMENTATION

Two instrument trays, a Unicondylar and a Patellofemoral tray are available for use with the RESTORIS MCK Implant System. Each tray contains instrumentation and implant trials specific to implementation of that procedure.

Both trays are required when performing a RESTORIS MCK Bicompartmental Inlay or Onlay procedure.*

All RESTORIS MCK implants require the use of the RIO therefore; a Standard MAKOplasty Instrument Set is also required.

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

PRE-OPERATIVE IMPLANT PLANNING

The primary purpose of pre-operative planning for the RESTORIS MCK implant system is implant sizing and alignment to bone anatomy. Fine tuning of the component position and orientation based on patient specific biomechanics and cartilage thickness will be completed during the intra-operative steps. Refer to the RIO System User Guide (PN 203857-15) and MAKOplasty Partial Knee Application User Guide (PN 206388-15) for software control details.

All varus/valgus and flexion/extension degree references are made with respect to the mechanical axis of the applicable bone. Internal/External rotations are with respect to the AP axis of the applicable bone.

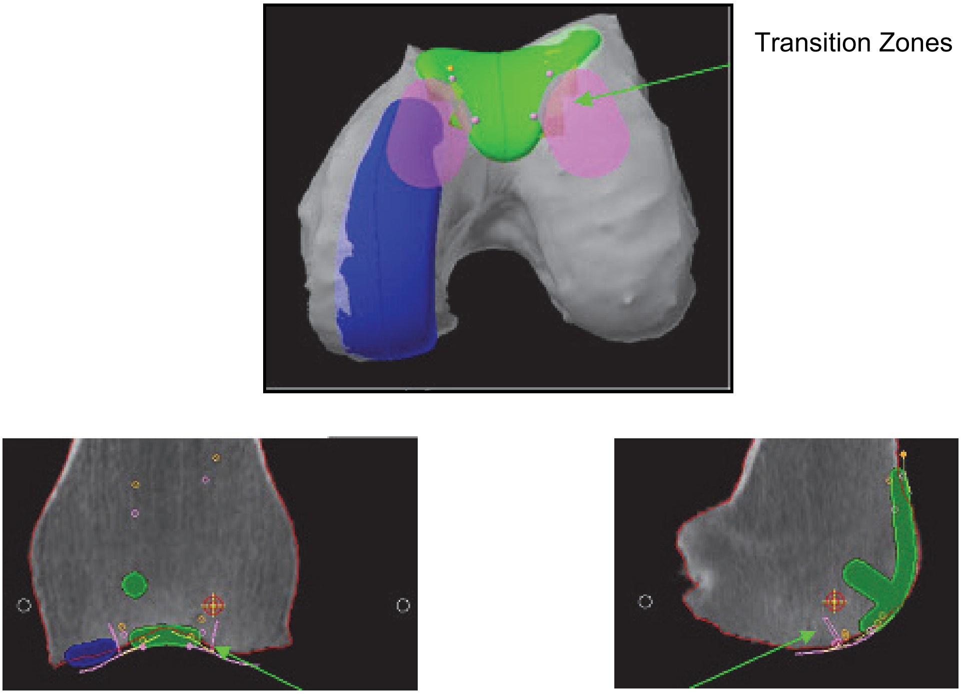
General Design Considerations for Implant Planning

- **Material**
  - CoCr and UHMWPE are the industry standard for component articulation.
  - Titanium was chosen for the baseplate because of its high strength and fatigue resistance.
  - All UHMWPE components are conventional compression molded polyethylene. They are gamma sterilized in an inert environment.
- **Fixation**
  - All metallic implant pegs have a 6.5 mm diameter, designed to have a slight press fit with a prepared peg hole when cemented.
  - The Tibial Inlay* has an outer cement channel for high fixation strength.
- **Compatibility**
  - All Femoral Condyle component sizes are compatible with all Tibial Inlay* or Onlay component sizes (full size compatibility).
  - All Patellofemoral (Trochlear) component sizes are compatible with all Patella component sizes (full size compatibility).
  - Component sizing for the Bicompartmental Femoral Condyle is limited to one size larger and one size smaller (1 up / 1 down) than the selected Patellofemoral (Trochlear) component. This aids in proper patella transitioning.

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

- **Bicompartmental Geometry**
  - The Femoral Condyle and Patellofemoral (Trochlear components) were designed from a single continuous femur articular surface from which the individual component shapes were outlined. This aids in inter component alignment and in patella transitioning from the trochlear groove to the femoral condyles during flexion.

    This continuous surface was sectioned into two implant visuals (transition zones) which act as surface extensions of the Trochlear component. The patellar transition zones move with the Trochlear component and can be turned on/off. The transition zones aid in Femoral positioning and Patella transitioning. The transition zones also have a separation indicator (wall) at 3 mm from the Patellofemoral (Trochlear) edge, which can be used as a reference to ensure that a 3 mm gap is maintained between the Femoral and Patellofemoral (Trochlear) implants.



Transition Zones

3 mm Distance Indicators

Figure 2. Trochlear transition zones with 3 mm distance indicators

- **Patellofemoral (Trochlear) Component Geometry**
  - The Patellofemoral Component trochlear groove pathway is curved proximally 6 degrees to align with the anatomic axis (when implant is planned at 0 degrees varus/valgus). The visual of the Patellofemoral (Trochlear) implant contains a Trochlear sulcus groove (Figure 3) which is a reference to the potential patella tracking pathway.

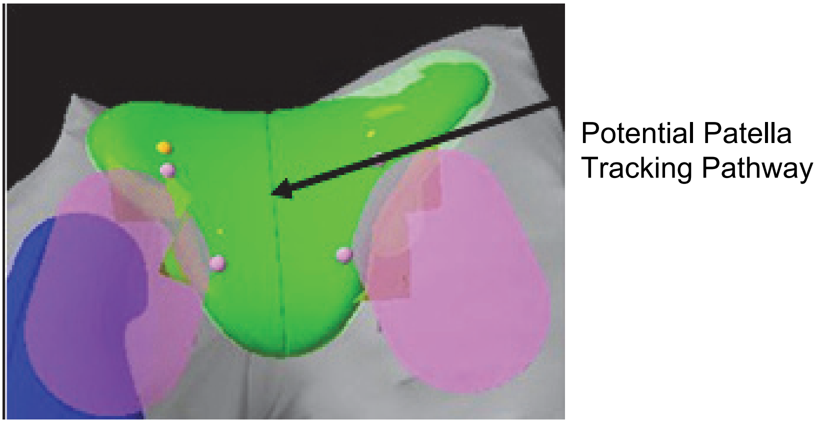


Figure 3. Trochlear Visual

- **Tibial Component Geometry**
  - All UHMWPE components have a minimum 6 mm thickness

    Tibial Onlay: An artificial gap is included in the Tibial Onlay component visual (see Figure 4). This gap does not alter the articular surface of the Insert or any of the geometry of the Baseplate. The bottom of the gap is the actual superior surface of the Baseplate Implant or Trial. The gap allows the user to distinguish the superior Baseplate surface from the inferior Insert surface during planning and to verify placement in CT View.

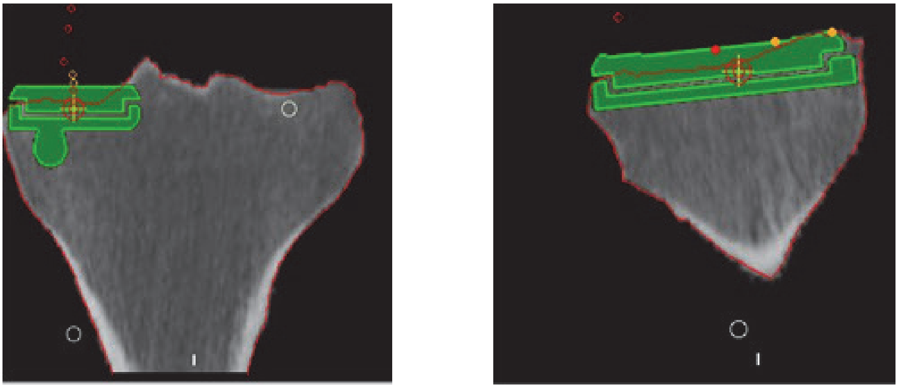


Figure 4. Tibial Onlay Visual

Tibial Inlay*: To assist in Implant Planning a reference groove is included in the Tibial Inlay* visual side wall perimeter (Figure 5). The center of the groove is 3.5 mm from the bottom of the implant and the top of the cement channel is 2.5 mm from the bottom of the implant. Per Appendix A, B and C the Inlay* should not be inset more than 3.5 mm below cortical bone surface.

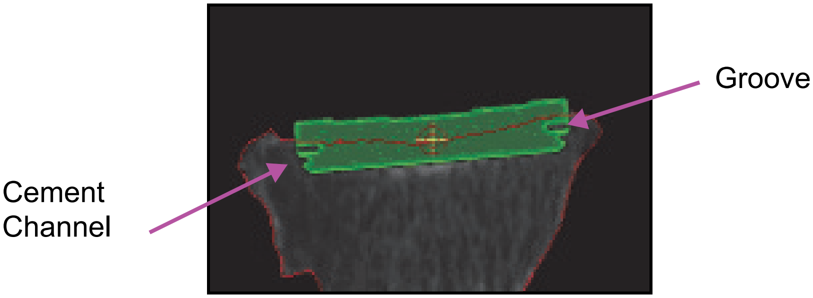


Figure 5. RESTORIS MCK Inlay Visualization*

Polymer Thickness Options: As outlined in the MAKOplasty Partial Knee Application User Guide (PN 206388-15) the available thicker poly options (Inlay*: 7.5 mm and 8.5 mm and Onlay: 9.0 mm and 10.0 mm) can be selected in the cases, post resection, where a thicker insert must be used.

⚠ *Always plan and resect using the thinnest poly. This feature is intended ONLY for analysis during trialing.*

When a thicker polyethylene trial is used in the joint, the corresponding thickness option should be selected in the drop down menu (Figure 5C). Then, as long as the VISUAL button is enabled, a visual of the surface of the trial will appear in the 3-D (Figure 5A) and 2-D (Figure 5B) views of Implant Planning. These visuals represent the superior surface of the selected Implant thickness. The CT views, Implant Planning Graph (Figure 5C) and Tibial Tracking points will update accordingly when a new poly thickness is selected.

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

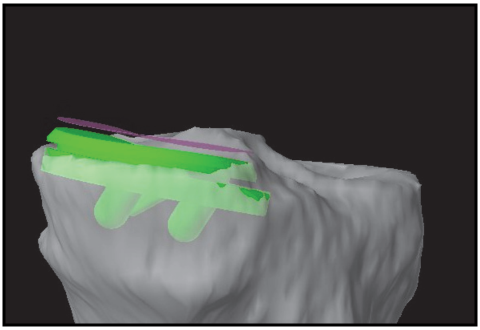


Figure 5A.3-D View of Poly Visual

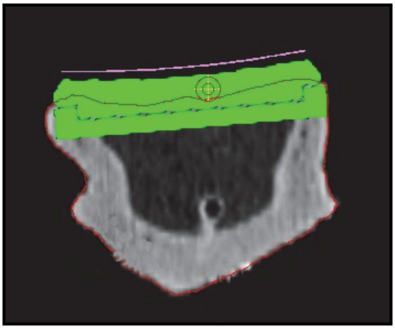
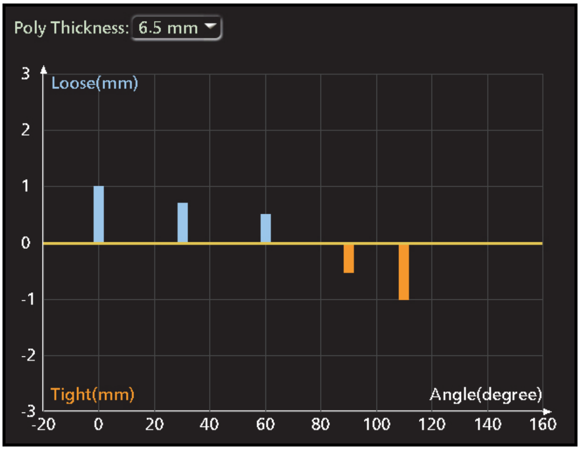


Figure 5B. 2-D View of Poly Visual



Poly Thickness: 6.5 mm

Loose(mm)
Tight(mm)
Angle(degree)
3
2
1
0
-1
-2
-3
-20
0
20
40
60
80
100
120
140
160

Figure 5C. Implant Planning Graph with Poly Thickness Selection

- **Femoral Condyle Geometry**
  - The Femoral Condyle component is designed for use when load bearing Range of Motion (ROM) is expected to be up to 155 degrees.
  - The Femoral Condyle component has a ‘patella relief’ feature on the anterior tip so as not to impinge with the patella or the Patella component during high flexion ROM.
  - The visual of the Femoral Condyle contains a high point groove (Figure 6) through the model that marks a reference for the potential tibial tracking pathway. During Intra-Op planning the groove can be used to align the Femoral Condyle to the tracking points collected during Joint Balancing (Pose Capture).

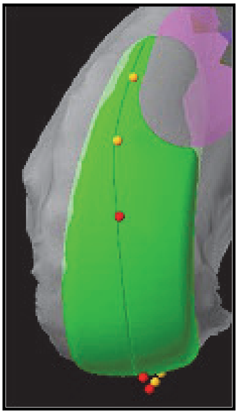


Figure 6. Femoral Condyle Visual

Unicondylar Inlay*/Onlay Pre-Operative Planning

For details regarding the following steps, refer to Appendix A for a step by step procedure to complete Medial Unicondylar Inlay*/Onlay Planning. Appendix A describes the steps necessary to complete a Bicompartmental Inlay*/Onlay, only the steps specific to a Medial Unicondylar procedure are relevant. Refer to Appendix C for a step by step procedure to complete Lateral Unicondylar Inlay*/Onlay Planning.

Planning Sequence

- **Tibial Inlay* / Onlay**
- **Femoral Condyle**

If the Tibial Inlay component is planned with less than a 2 mm rim of bone on the anterior, posterior, or medial sides, the rim may be removed or fractured during resection.*

Adjustments to the plan from the nominal may be necessary to match specific patient anatomy.

Patellofemoral Pre-Operative Planning

For details regarding the following steps, refer to Appendix A for a step by step procedure to complete Patellofemoral Planning. Appendix A describes the steps necessary to complete a Bicompartmental Inlay*/Onlay, only the steps specific to a Patellofemoral procedure are relevant.

Planning Sequence

- **Patellofemoral (Trochlear)**

External rotation of the Patellofemoral (Trochlear) component is not recommended as it will decrease the lateral patella jump height and increase the risk of lateral patella subluxation.

Do not put the Patellofemoral (Trochlear) component in more than 2° valgus as this will align the trochlear groove away from the anatomic axis of the femur and increase the risk of lateral patella subluxation.

Adjustments to the plan from the nominal may be necessary to match specific patient anatomy.

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

Bicompartmental Pre-Operative Planning

For details regarding the following steps, refer to Appendix A for a step by step procedure to complete Bicompartmental Planning.

Planning Sequence

- **Tibial Inlay*/Onlay**
- **Bicompartmental (Patellofemoral + Medial Femoral Condyle)**
- **Patellofemoral (Trochlear)**
- **Femoral Condyle**

⚠ *If the tibial Inlay* component is planned with less than a 2 mm rim of bone on the anterior, posterior, or medial sides, the rim may be removed or fractured during resection.*

⚠ *External rotation of the Patellofemoral (Trochlear) component is not recommended as it will decrease the lateral patella jump height and increase the risk of lateral patella subluxation.*

⚠ *Do not put the Patellofemoral (Trochlear) component in more than 2° valgus as this will align the trochlear groove away from the anatomic axis of the femur and increase the risk of lateral patella subluxation.*

📌 *Adjustments to the plan from the nominal may be necessary to match specific patient anatomy.*

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

BONE PIN PLACEMENT

For additional information regarding bone pin placement, see the MAKOplasty Partial Knee Application User Guide (PN 206388-15).

For Patellofemoral or Bicompartmental procedures, femoral bone pins might need to be more proximally placed to accommodate Patellofemoral (Trochlear) and Patella preparation.

INCISION AND EXPOSURE

Medial Incision and Exposure

1. With the knee flexed at about 45°, create a skin incision directly over the median plane of the knee. The underlying arthrotomy will be placed more medially than the skin incision to prevent wound complications. As a guide for a minimally invasive technique, the incision should extend from the inferior border of the patella to approximately 2 cm below the tibial plateau. Extend the incision proximally or distally as needed for adequate visualization.
2. Undermine the subcutaneous tissues and place retractors to expose the medial retinaculum.
3. Make a medial parapatellar arthrotomy through the medial retinaculum, capsule, and synovium. If necessary, extend the arthrotomy proximally by making a medial snip of the Vastus Medialis Oblique (VMO) at the distal insertion site of the patella (this will aid in exposure and help mobilize the patella). The length of the incision and arthrotomy must be sufficient to enable proper patella retraction for femoral prosthesis insertion, femoral registration, and tibial registration.
4. Inspect all compartments and evaluate the integrity of the Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) to confirm the indications for a unicondylararthroplasty.
5. Elevate the medial capsule from the proximal tibia to the mid-sagittal plane. For an Inlay* procedure, this may not be required because less tibial exposure is needed. A medial collateral release should not be performed.
6. Debulk the fat pad as needed for exposure and resect the visible medial meniscus.
7. Reflect patella laterally to expose tibiofemoral joint space.
8. Trim any portions of loose or torn meniscus and release soft tissue from the anterior surface of the tibia, as needed, for improved exposure and registration.

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Lateral Incision and Exposure

1. With the knee flexed at about 45°, create a skin incision directly over the median plane of the knee as lateral soft tissues are extremely thin. The underlying arthrotomy will be placed more laterally than the skin incision to prevent wound complications. As a guide for a minimally invasive technique, the incision should extend from the superior pole of the patella to approximately 2 cm below the tibial plateau. Extend the incision proximally or distally as needed for adequate visualization.
2. Undermine the subcutaneous tissues and place retractors to expose the lateral retinaculum.
3. Make a lateral parapatellar arthrotomy through the lateral retinaculum, capsule, and synovium. The length of the incision and arthrotomy must be sufficient to enable proper patella retraction for femoral prosthesis insertion and to allow for tibial registration. In certain circumstances, exposure can be enhanced by lateralizing the arthrotomy 5-10 mm more lateral to the patella. A 'T'-shaped cut in the arthrotomy can help to relax the soft tissues for improved visualization and easier retraction of the patella medially.
4. Inspect all compartments and evaluate the integrity of the Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) to confirm the indications for a unicondylar arthroplasty.
5. For an Onlay procedure, elevate the lateral capsule from the proximal tibia until Gerdy's tubercle is released. For an Inlay* procedure, this may not be required because less tibial exposure is needed. A lateral collateral release should not be performed.
6. Debulk the fat pad as needed for exposure and resect the visible lateral meniscus. Use caution interiorly to preserve the intermeniscal ligament and its attachment to the proximal tibia. Release of this ligament can destabilize the medial meniscus.
7. Reflect patella medially to expose tibiofemoral joint space.
8. Trim any portions of loose or torn meniscus and release soft tissue from the anterior surface of the tibia, as needed, for improved exposure and registration.

Patellofemoral Incision and Exposure

1. With the knee flexed at about 45°, create a skin incision directly over the median plane of the knee. The underlying arthrotomy will be placed more medially than the skin incision to prevent wound complications. As a guide for a minimally invasive technique, the incision should extend from the superior border of the patella to the top of the tibial plateau. Extend the incision proximally or distally as needed for adequate visualization.

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

2. Undermine the subcutaneous tissues and place retractors to expose the medial retinaculum.
3. Make a medial sub-vastus or mid-vastus arthrotomy through the medial retinaculum, capsule, and synovium. The length of the incision and arthrotomy must be sufficient to enable proper patella retraction for trochlear prosthesis insertion and femoral registration.
4. Inspect all compartments and evaluate the integrity of the Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) to confirm the indications for a patellofemoral arthroplasty.
5. Debulk the fat pad as needed for exposure and elevate any suprapatellar synovium for trochlear exposure.
6. Reflect patella laterally to expose patellofemoral joint space.

Bicompartmental Incision and Exposure

1. With the knee flexed at about 45°, create a skin incision directly over the median plane of the knee. The underlying arthrotomy will be placed more medially than the skin incision to prevent wound complications. As a guide for a minimally invasive technique, the incision should extend from the superior border of the patella to approximately 2 cm below the tibial plateau. Extend the incision proximally or distally as needed for adequate visualization.
2. Undermine the subcutaneous tissues and place retractors to expose the medial retinaculum.
3. Make a medial sub-vastus or mid-vastus arthrotomy through the medial retinaculum, capsule, and synovium. The length of the incision and arthrotomy must be sufficient to enable proper patella retraction for femoral prosthesis insertion, femoral registration, and tibial registration.
4. Inspect all compartments and evaluate the integrity of the Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) to confirm the indications for a unicondylar arthroplasty.
5. Elevate the medial capsule from the proximal tibia to the mid-sagittal plane. For an Inlay* procedure, this may not be required because less tibial exposure is needed. A medial collateral release should not be performed.
6. Debulk the fat pad as needed for exposure and resect the visible medial meniscus.
7. Reflect patella laterally to expose tibiofemoral and patellofemoral joint space.
8. Trim any portions of loose or torn meniscus and release soft tissue from the anterior surface of the tibia, as needed, for improved exposure and registration.

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

PRE-RESECTION JOINT BALANCING

Philosophy

For manual medial unicondylar implantation, it is typical for the surgeon to evaluate post-resection restoration by insuring the femoral-tibial gap and limb alignment are acceptable in extension, flexion and for intermediate leg poses while inducing an appropriately applied valgus stress.

During a MAKOplasty, ligament tension and limb alignment can be established prior to resection and implantation by ‘capturing’ the leg in corrected poses and tension such that the final implant placement will achieve the desired result. In other words, with precise planning prior to resection, it is possible to achieve proper ligament tension and limb alignment after implantation.

Joint Balancing is not necessary for a Patellofemoral only procedure because the tibia is not registered.

Either the tibia or the femur can be fixed while the other moves relative to the fixed bone during Joint Balancing. See the MAKOplasty Partial Knee Application User Guide (PN 206388-15) for instructions on setting this in Surgeon Preferences.

Eliminate Osteophyte / Adhesion Effects on Joint Mechanics

The Pre-Resection Joint Balancing data must not be adversely influenced by effects of the osteoarthritic pathology - e.g. osteophytes, capsular adhesions, and osteochondral defects. Osteophytes interfering with Medial Collateral Ligament (or Lateral Collateral Ligament for lateral UKA) function should be removed and capsular adhesions interfering with knee function should be relieved. With these impediments removed, it will be possible to achieve correct knee kinematics and tissue tension during passive manipulation throughout the full range of motion.

Pre-Resection Joint Balancing

To achieve correct restoration of the osteochondral defects, joint balancing pose capture must occur with the collateral ligament properly tensioned. Doing so will provide correct bone spacing (extension and flexion gaps) during Intra-Op Implant Planning such that after resection and component implantation, knee mechanics will be properly restored throughout leg range of motion.

Although this step is referred to as ‘Joint Balancing’, desired joint balancing is achieved in Intra-Op Implant Planning using the data gathered in this step (bone spacing with properly tensioned ligaments).

Ensure osteophytes are removed prior to taking pose captures for Joint Balancing.

Attempt to apply the appropriate varus or valgus (valgus - medial, varus - lateral) moment to the tibia at each pose during Joint Balancing for proper tensioning of ligaments.

It is recommended that the leg is passively corrected to be slightly under corrected for the ‘extension’ pose capture (5-10° flexion).

Pre-Resection Joint Balancing is necessary for enabling full use of the intra-operative implant planning features. Medical standard of practice is to acquire a minimum of 4 poses (full extension, full flexion, and 2 additional angles in between). More than 4 pose captures are possible however it is up to the surgeon’s discretion as to how many poses to capture.

Recommended Pose Captures for Joint Balancing

Listed below are the 4 minimum recommended poses, more poses can be captured as needed to ensure a successful implant plan.

- 5°-10° (Extension gap balancing)
- 45° (Mid-flexion gap balancing)
- 90° (Flexion gap balancing)
- 100°-120° (Maximum flexion) - this pose is critical for planning the posterior tibiofemoral articulation during Intra-Operative Planning, especially for a Lateral Unicondylar procedure.

Refer to Appendix B for step by step visual instructions.

INTRA-OPERATIVE IMPLANT PLANNING

During intra-operative planning, patient specific information gathered in the ‘Joint Balancing’ step is used to adjust the pre-operative implant plan to achieve implant component positions suitable for resection. Software functionality for this step can be found in the MAKOplasty Partial Knee Application User Guide (PN 206388-15).

The green models displayed on the ‘Implant Planning’ software page represent the final locations of the implanted components. However, due to the interaction of the user with the stereotactic boundaries, the actual resection may be slightly wider at the implant walls. To prevent malalignment and to preserve bone, always allow sufficient space between components and size appropriately.

Unicondylar Inlay* / Onlay Intra-Operative Planning

For details regarding the following steps, refer to Appendix B for a step by step procedure to complete Medial Unicondylar Inlay*/Onlay Planning. Appendix B describes the steps necessary to complete a Bicompartmental Inlay*/Onlay, only the steps specific to a Medial Unicondylar procedure are relevant. Refer to Appendix C for a step by step procedure to complete Lateral Unicondylar Inlay*/Onlay Planning.

Planning Sequence

- **Tibial Inlay*/Onlay**
- **Femoral Condyle**

If the Tibial Inlay component is planned with less than a 2 mm rim of bone on the anterior, posterior, or medial sides, the rim may be removed or fractured during resection.*

Adjustments to the plan from the nominal may be necessary to match specific patient anatomy.

RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.

Patellofemoral Intra-Operative Planning

For details regarding the following steps, refer to Appendix B for a step by step procedure to complete Patellofemoral Planning. Appendix B describes the steps necessary to complete a Bicompartmental Inlay*/Onlay, only the steps specific to a Patellofemoral procedure are relevant.

Planning Sequence

- **Patellofemoral (Trochlear)**

Ensure the Patellofemoral (Trochlear) component is not in excessive external rotation or valgus, as these will decrease the lateral patella jump height and increase the risk of lateral patella subluxation.

The proximal edge of the Patellofemoral (Trochlear) component can transition into the bone in three ways:
Proud - the articular surface is proud (cemented surface rests on top of the bone)
Medium - halfway between proud and flush
Flush - the articular surface is flush with the bone

Bicompartmental Intra-Operative Planning

For details regarding the following steps, refer to Appendix B for a step by step procedure to complete Bicompartmental Planning.

Planning Sequence

- **Tibial Inlay*/Onlay**
- **Patellofemoral (Trochlear)**
- **Femoral Condyle (Medial)**

Ensure the Patellofemoral (Trochlear) component is not in excessive external rotation or valgus, as it will decrease the lateral patella jump height and increase the risk of lateral patella subluxation.

The proximal edge of the Patellofemoral (Trochlear) component can transition into the bone in three ways:
Proud - the articular surface is proud (cemented surface rests on top of the bone)
Medium - halfway between proud and flush
Flush - the articular surface is flush with the bone

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

Implant Planning After Initial Resection

⚠ *Care must be taken when choosing to adjust an implant plan after resection has taken place. Since the software tracks only the latest change to an implant plan, a plan can be created which overlaps a previous resection. To prevent implant malalignment or component impingement, the operative surgeon should check component placement with the RIO probe before a change to the plan is made.*

Any component can be re-planned and/or resized (and subsequently resected again) after an initial resection using any of the implant planning features. The following issues should be considered before changing a component plan after initial resection:

- Any system configuration (Unicondylar, Patellofemoral or Bicompartmental)
    - The software will not save the previous plan once a change to the plan is made.The old plan will be overwritten. The ‘undo’ button may be used, but only the latest (new) plan will be applied when returning to the ‘Bone Preparation’ page
    - Any change which causes the implant to become more proud of the bone will not be represented in the software (i.e., resected bone cannot be restored).
    - A conversion from Tibial Inlay* to Onlay will align the initial Tibial Onlay plan with the articular surface of the previous Inlay* component

📌 *Detailed instructions on software functionality can be found in the MAKOplasty Partial Knee Application User Guide (PN 206388-15).*

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

BONE PREPARATION

Even with stereotactic boundaries, the burr can contact nearby tissue. To avoid risk of serious injury, use a retractor to protect the medial or lateral collateral ligament during Tibial Onlay resection.

To create proper press fit with the implant peg, gently plunge the burr only once then release the trigger and move to the next step. Plunging more than once can create a larger hole and prevent the peg from fitting snuggly.

Table 1 is a list of resection steps for each procedure. All steps marked with an ‘X’ are to be completed with the 6 mm Ball Burr; others are noted. All of the listed steps should be implemented using the technique listed in this manual. The order of resection, tibial keel router choice and Inlay* pattern are surgeon preference combinations that can be adjusted in the Preferences page.

Table 1. Resection Steps for RESTORIS MCK
(All steps marked with an ‘X’ are to be completed with the 6 mm Ball Burr)

	Unicondylar (Uni) Inlay*	Unicondylar (Uni) Onlay	Patellofemoral	Bicompartmental Inlay*	Bicompartmental Onlay
Femoral Surface	x	x		x	x
Femoral Post 1	x	x		x	x
Femoral Post 2	x	x		x	x
Femoral Keel[1]	x	x		x	x
Tibial Inlay* Surface[4]	x			x	
Tibial Onlay Surface		x			x
Tibial Post 1		x			x
Tibial Post 2		x			x
Tibial Keel*[2]		2 mm/1.4 mm Router			2 mm/1.4 mm Router
Patellofemoral Surface			x	x	x
Patellofemoral Post 1			x	x	x
Patellofemoral Post 2			x	x	x
Patellofemoral Post 3			x	x	x

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

Table 1. Resection Steps for RESTORIS MCK (All steps marked with an ‘X’ are to be completed with the 6 mm Ball Burr)					
	Unicondylar (Uni) Inlay*	Unicondylar (Uni) Onlay	Patellofemoral	Bicompartmental Inlay*	Bicompartmental Onlay
Patella Resection[3]			Manual Preparation	Manual Preparation	Manual Preparation

Notes:

[1] Femoral keel resection is only applicable to sizes 3-8.

[2] The Tibial Onlay Keel may be prepared in a medial or lateral procedure by impacting the Tibial Onlay Trial, however RIO access for a lateral unicondylar procedure can be challenging so using the trial is the recommended method of lateral keel resection.

[3] Preparation of the patella uses the Patella Preparation Section of this manual.

[4] The Tibial Inlay* has a surgeon preference setting that allows resection with (Figure 8) or without (Figure 7) the clover pattern boundary. Using the clover pattern leaves four small sections of bone that fit closer to the Inlay* component to help stabilize the Inlay* Trial and Implant during cementing.

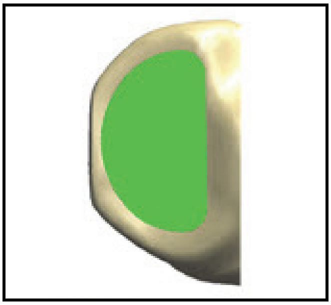


Figure 7.RESTORIS MCK Inlay Resection WITHOUT Clover Pattern*

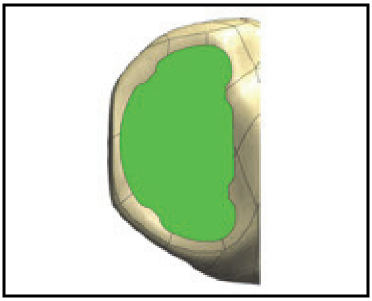


Figure 8. RESTORIS MCK Inlay Resection WITH Clover Pattern*

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

Conversion from RESTORIS MCK Inlay* to RESTORIS MCK Onlay

Under no circumstances should a conversion from the RESTORIS MCK Implant System to the RESTORIS Implant System be performed. The implant geometries are not equivalent. Mixing incompatible implant systems could shorten implant life.

Conversion from the RESTORIS MCK Inlay* to the RESTORIS MCK Onlay can occur at any time. This conversion is done at the discretion of the operative surgeon. To convert, follow the steps outlined below.

1. Clear RESTORIS MCK Inlay* instrumentation and trials from surgical field before bringing in RESTORIS MCK Onlay instrumentation and trials.
2. Select the new Tibial component per the MAKOplasty Partial Knee Application User Guide (PN 206388-15).
3. Return to Implant Planning and make any adjustments to the plan to ensure proper Tibial Onlay placement.
4. Proceed to RESTORIS MCK Onlay resection.

When converting from a RESTORIS MCK Inlay to RESTORIS MCK Onlay system (Bicompartmental or Uni), the software application will align the articular surfaces of each tibial component at the same height in the 'Implant Planning' page.*

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

MANUAL PEG AND KEEL PREPARATION

Prerequisites

The manual resection of the RESTORIS MCK is for use when implant surface pockets have been resected and only the pegs and keels need resection or correction.

No instrumentation exists for resecting RESTORIS MCK surface manually. Available instrumentation is applicable to peg and keel resection only.

Manual Instrumentation

The RESTORIS MCK Manual Technique uses the RESTORIS MCK Manual Instrument Set.

Instruments are provided separately in re-usable/sterilizable trays. Trays include various tools (e.g., templates and drills) needed for a RESTORIS MCK manual procedure.

The steps in this section are guidelines and do not constitute a complete surgical technique.

Femoral Condyle Component

Affix the Femoral Template to the resected bone pocket using the Headed Bone Pins and the Pin Pusher (Figure 9).

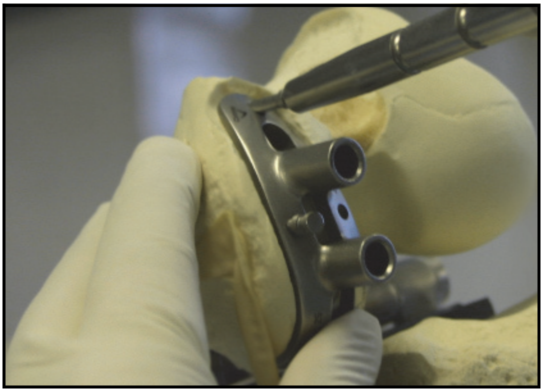


Figure 9

Drill the peg holes for the Femoral Condyle Implant using the Femoral Peg Drill (Figure 10).

Mark the position of the keel using a sterile marker.

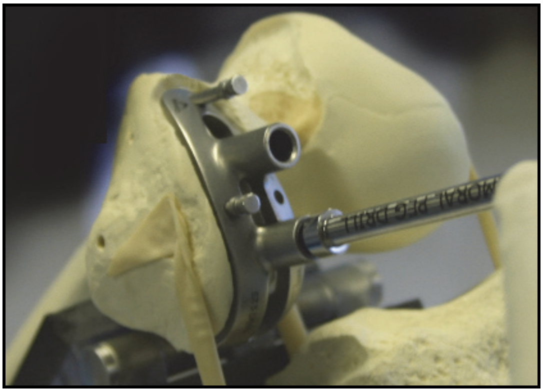


Figure 10

Remove the Headed Bone Pins from the bone using the Pin Puller and remove the Femoral Template (Figure 11).

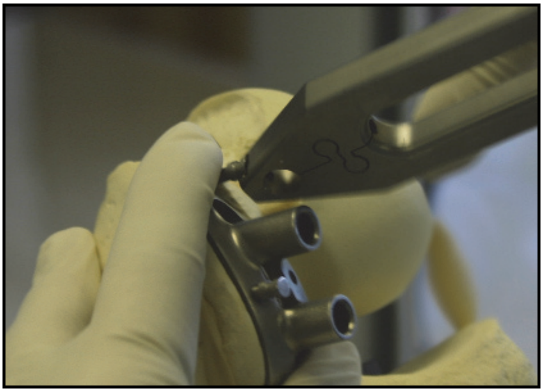


Figure 11

Resect the keel using a 6 mm burr to the depth shown on the Femoral Template (Figure 12).

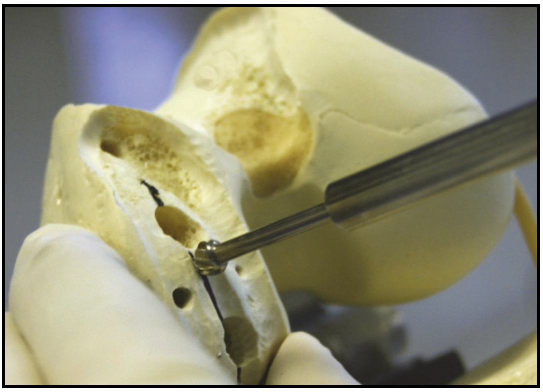


Figure 12

Tibial Onlay Baseplate

Attach the Onlay Handle to the Baseplate Template. Align the Baseplate Template to the resected tibial profile and impact into place with a mallet. Confirm that the template is fully seated on the tibia.

Drill peg holes for the Tibial Baseplate using the Patellar/Tibial Peg Drill (Figure 13).

Remove Baseplate Template from the tibia.

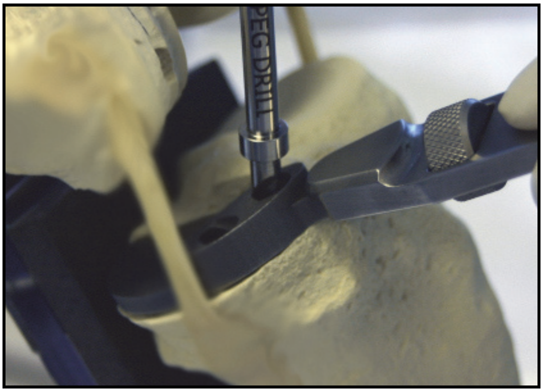


Figure 13

Patellofemoral Template

Affix the Patellofemoral Template to the resected bone pocket using the Headed Bone Pins and the Pin Pusher (Figure 14)

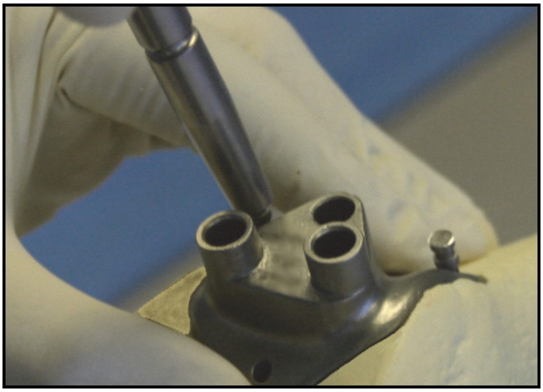


Figure 14

Drill the peg holes for the Patellofemoral (Trochlear) Implant using the Femoral Peg Drill (Figure 15).

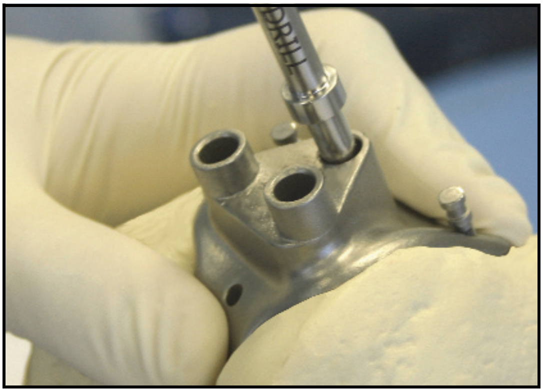


Figure 15

Remove the Headed Bone Pins using the Pin Puller and remove the Patellofemoral Template (Figure 16).

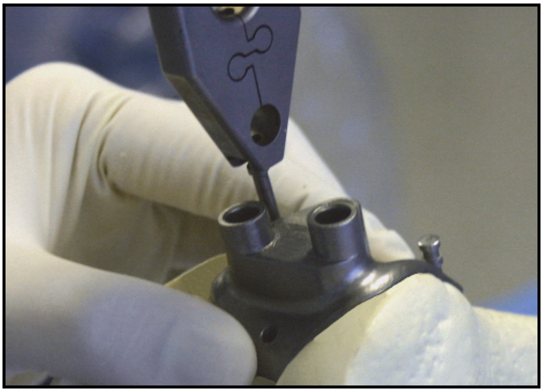


Figure 16

TRIAL REDUCTION AND IMPLANTATION

The steps in this section are guidelines and do not constitute a complete surgical technique.

⚠ *Care should be used in the handling of the implant components to minimize damage to the component surfaces. The surgeon should use care to ensure complete cement support on all parts of the prosthesis contacting resected bone. It is important to pressurize cement into both tibial and femoral peg holes.*

⚠ *Implants must not be reused. The surgeon must not allow damage to polished bearing surfaces because this may accelerate wear of the implant components. Any alteration or damage to an implant component may result in failure under load. Any prostheses so damaged must not be used.*

⚠ *Care should be used when inserting (impacting) a trial or implant. If the initial fit is too tight, impaction could damage the bone. Return to the BONE PREPARATION section if more bone must be removed.*

⚠ *Do not place excessive off-center shear loads on the implant component until the cement has cured. These types of loads could cause improper implant-to-cement-to-bone fixation and could shorten implant life.*

⚠ *For proper fixation, the knee must be kept stationary while cement cures. If the leg is moved during curing, the implant components may move from their intended positions.*

⚠ *Multiple cement batches should be used when cementing multiple implants to maintain a consistent and suitable cement viscosity that 1) enables all implants to fully mate to resected bone to ensure desired alignment, 2) enables sufficient cement interdigitation into the cancellous bone to ensure proper fixation, and 3) enables the user to apply an even distribution of compressive force to ensure the implant remains stable while the cement is setting.*

Femoral Condyle

1. Insert the selected size Femoral Trial, impact as applicable.

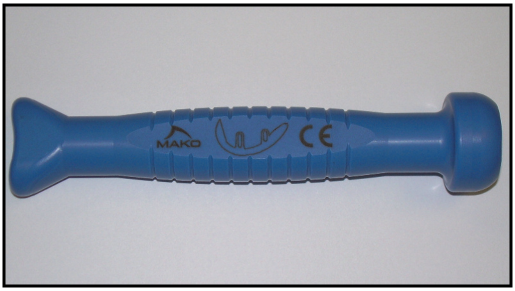


Figure A: One-Piece RESTORIS MCK Femoral Impactor

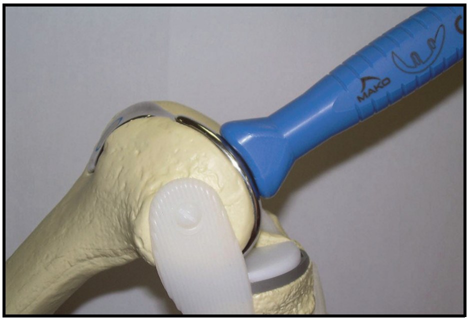


Figure B: Proper impaction technique when using the Femoral Impactor. Align impactor with Trial / Implant Peg axis.

2. Rongeur any proud cartilage and bone.

To facilitate component insertion it may help to insert the Femoral Condyle component prior to the Tibial component.

3. With applicable Tibial Trial in place, move the knee through a full range of motion.
4. Remove Femoral Trial by screwing the Slaphammer into the threaded hole and extracting the assembly.
5. Use pulsed lavage or similar technique to remove fatty deposits from the cancellous porous structure and pat dry.
6. Apply cement to the Femoral Condyle. For proper fixation, ensure cement is applied to the posterior face of the Femoral Condyle.
7. Apply cement to the distal resected cavity and firmly pack the cement into the bone using your fingers.
8. Place the Femoral Condyle onto the femur and impact with the Femoral Impactor. Confirm that the implant is fully seated.
9. Carefully remove all excess extruded cement.
10. With the Femoral Condyle centrally loading the Tibial component, hold the knee joint stationary until cement has cured.

Tibial Onlay

To facilitate component insertion it may help to insert the Femoral Condyle component prior to the Tibial component.

1. Insert the selected size Tibial Baseplate Trial (impact as applicable) and Insert Trial.

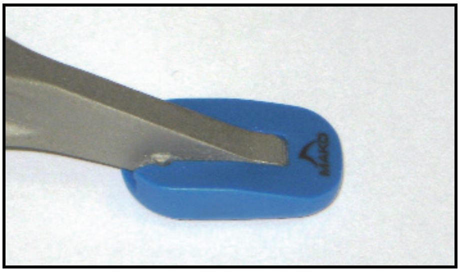


Figure A: Correct assembly of the Tibial Baseplate-Inlay Impactor - Ensure that the Impactor Head is completely snapped onto the Impactor Handle before use.*

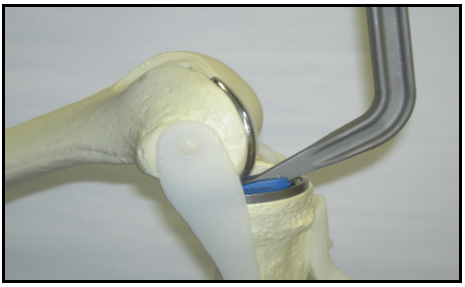


Figure B: Proper impaction technique when using the Tibial Baseplate-Inlay Impactor*

2. With the applicable Femoral Trial in place, move the knee through a full range of motion.
3. Remove Tibial Trial components. (See figures below.)

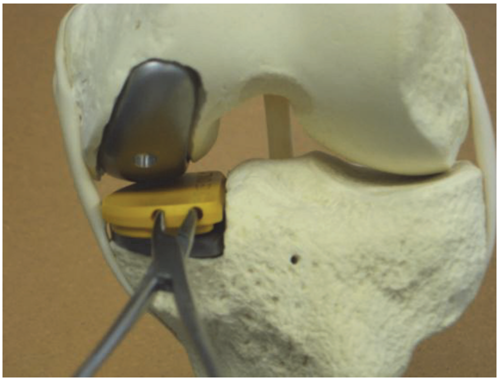


Figure A: Using a Hemostat or similar instrument, insert the Hemostat prongs into the holes on the anterior edge of the Trial Insert, lift up and pull out to extract the Trial.

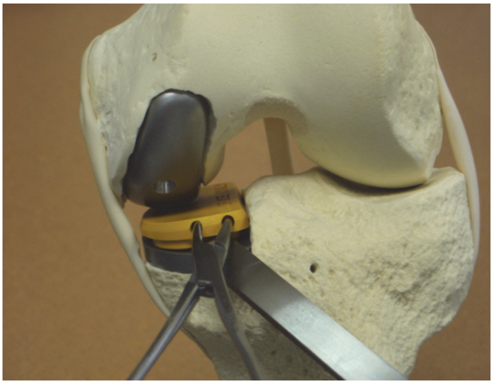
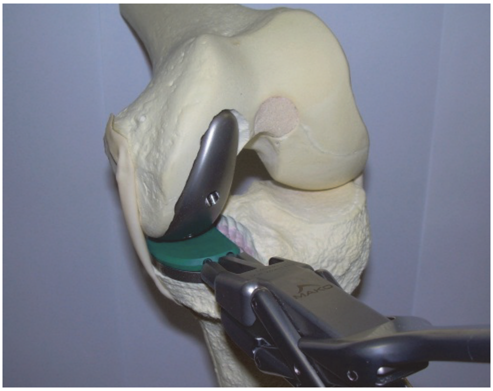


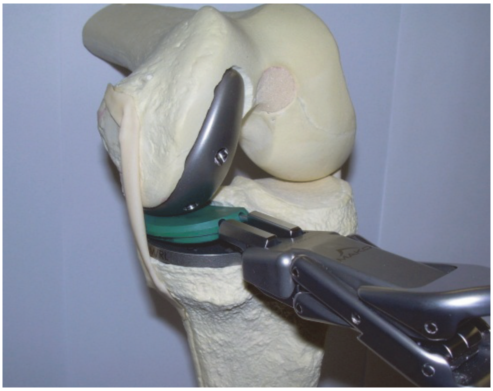
Figure B: Using a Hemostat or similar instrument, insert the prongs into the removal holes at the front of the Trial Insert and lift up to get an Osteotome under the trial. Grasp the trial firmly and extract the Trial Insert from the Trial Baseplate.

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

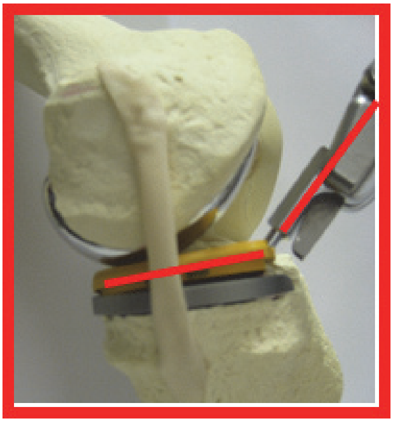
a. If using the Onlay Insert Extractor, perform the following steps:
   i. Orient the Onlay Insert Extractor so the MAKO logo is visible (facing towards the femur), and insert the tips of the instrument completely into the holes of the Insert Trial.



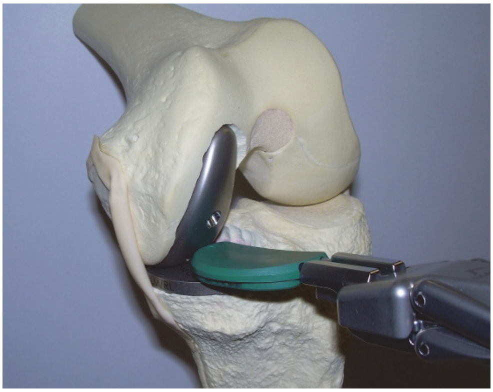
   ii. Squeeze the handles of the instrument to lift the Insert Trial from the Tibia Baseplate. Keep the Extractor parallel to the Insert Trial. Moving the Extractor up or down while engaged with the Trial will damage the Trial.



***DO NOT** lever the Onlay Insert Trial from the Tibia Baseplate. This may damage the Onlay Insert Trial.*



   iii. Extract the Insert Trial by squeezing the handles and pulling the Insert Trial out of the joint.



4. Use pulsed lavage or similar technique to remove fatty deposits from the cancellous porous structure and pat dry.
5. A wet cloth may be placed behind the tibia to catch escaping cement during impaction.
6. Apply cement to the Tibial Baseplate; ensuring excessive cement is not applied posteriorly.
7. Apply cement to the resected tibia and firmly pack the cement into the bone using your fingers.
8. Place the Tibial Baseplate onto the tibia and impact with the Inlay*-Baseplate Impactor, starting posteriorly and work anteriorly allowing cement to escape anteriorly. Impact vertically into final position. Confirm that the implant is fully seated.
9. Carefully remove all excess extruded cement.
10. If a wet cloth was used posteriorly, remove it.
11. Place Onlay Insert Trial into the Tibial Baseplate implant.
12. With the Femoral Condyle centrally loading the Onlay Insert Trial, hold the knee joint stationary until cement has cured.
13. With cement cured on the Femoral and Baseplate Implants, move the knee through a full range of motion to ensure desired insert thickness is trialed.

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

14. Remove Onlay Insert Trial (see figures in step 3.)

Verify that the surfaces and walls of the Baseplate are free of soft tissue, cement remnants and any other obstruction.

Check the Onlay Insert alignment with the Tibial Baseplate before impacting.

15. Secure the posterior locking 'mechanism' of the Onlay Insert under the posterior capture feature of the Tibial Baseplate. A correctly positioned Insert will have its front edge parallel to the top edge of the Baseplate pocket as illustrated in Figure 17.

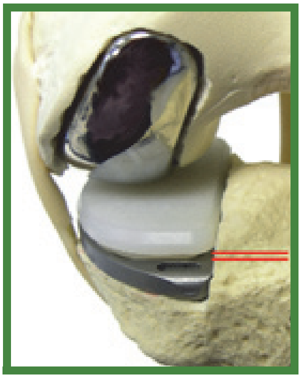


Figure 17

In this position, the anterior chamfer of the Insert should align with the corresponding pocket chamfer of the Tibial Baseplate as shown by the cross-section view in Figure 18.

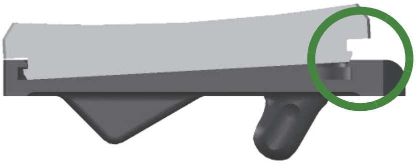


Figure 18

To avoid slippage of the Onlay Insert, use only the Onlay Insert Impactor for impaction.

Note that an incorrectly positioned Insert will have its front edge at an acute angle with the top edge of the Baseplate pocket as shown in Figure 19. In this scenario, the Insert must first be positioned correctly before proceeding.

16. With the Insert correctly positioned use the Onlay Insert Impactor at a 30-45° angle to impact the anterior edge of the Insert and lock it into the Tibial Baseplate. The impaction should be sharp enough to fully seat the Onlay Insert with one hit. Confirm that the implant is fully seated.

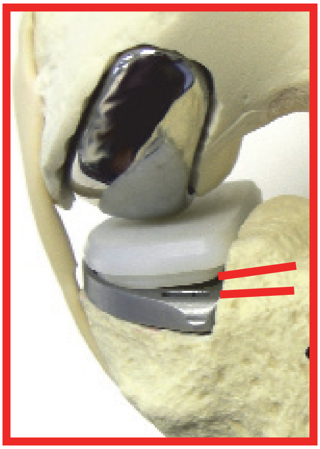


Figure 19

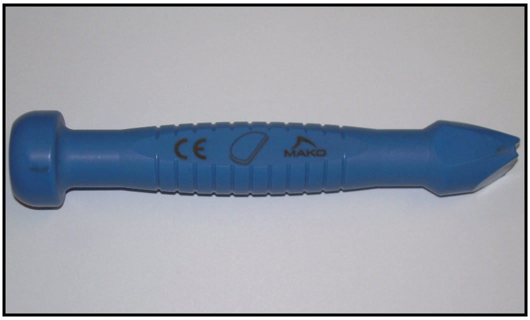


Figure A: One-Piece RESTORIS MCK Onlay-Insert Impactor.

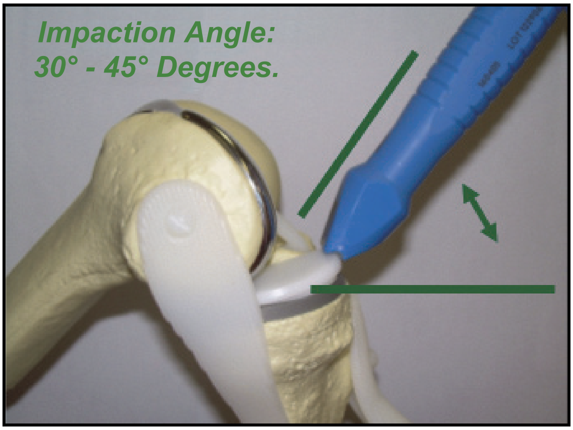


Figure B: Proper impaction technique when using the Onlay Insert Impactor.

It may be necessary to mix the cement in multiple batches to ensure that distributed pressure is applied to the Inlay throughout the entire curing process.*

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

Tibial Inlay*

To facilitate component insertion it may help to insert the Femoral Condyle component prior to the Tibial component.

1. Insert the selected size Tibial Inlay* Trial.

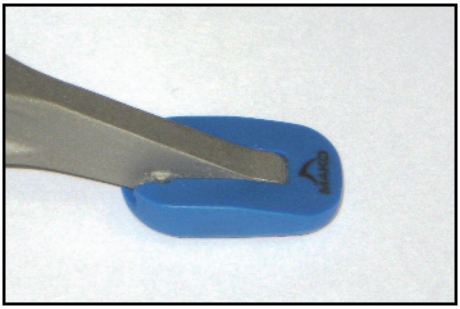


Figure A: Correct assembly of the Tibial Impactor - Ensure that the Baseplate-Inlay Impactor Head is completely snapped onto the Impactor Handle before use.*

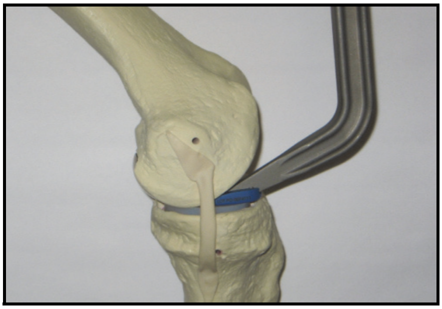


Figure B: Proper impaction technique when using the Tibial Baseplate-Inlay Impactor*

2. With the applicable Femoral Trial in place, move the knee through a full range of motion.
3. Remove the Tibial Inlay* Trial component.
4. Use high pressure pulsed lavage (right angle attachment works well) or similar technique to remove fatty deposits from the cancellous porous structure. Dry the surface with a sponge filling the cavity under firm digital pressure or similar technique prior to cementing. The open porous structure improves cement interdigitation.
5. A wet cloth may be placed behind the tibia to catch escaping cement during impaction.
6. Immediately apply cement to the resected cavity using a cement gun or firmly pack the cement into the bone using your fingers. Cement should be inserted as soon as it becomes workable (not shiny and sticky).
7. Apply cement to the Inlay* bottom and peripheral cement channel.
8. Immediately place the Tibial Inlay* into the cavity and compress it evenly and forcefully using finger or flat instrument pressure (e.g., freer elevator or the Inlay*-Baseplate Impactor).
9. Carefully remove all excess extruded cement.
10. If a wet cloth was used posteriorly, remove it.

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

11. Apply and maintain distributed pressure on the central articular surface of the Inlay*. This may extrude additional cement, which should now be removed. Do not allow the implant to move until the cement has fully cured. Pressure can be maintained by direct finger compression or with the assistance of the Inlay*-Baseplate Impactor. Distributed pressure is important, particularly in the anterior/posterior direction, to avoid tilting of the component in the sagittal plane within the prepared cavity during cement curing.

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

Patellofemoral (Trochlear)

1. Insert the selected size Patellofemoral (Trochlear) Trial, impact as applicable.

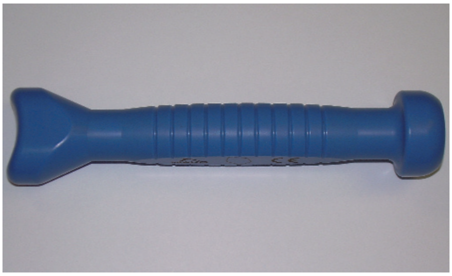


Figure A: One-Piece MCK Patellofemoral Impactor

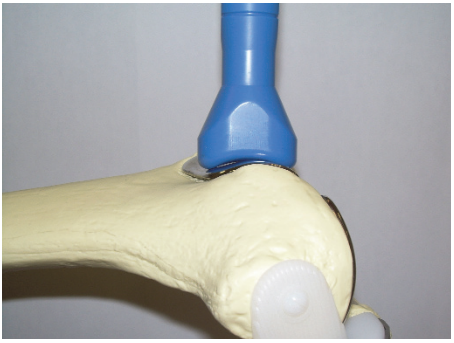


Figure B: Proper impaction technique when using the Patellofemoral Impactor.

2. Rongeur any proud cartilage and bone.
3. With the applicable Patella Trial in place, confirm smooth patella transitioning.
4. Remove Patellofemoral (Trochlear) Trial by screwing the Slaphammer into the threaded hole and extracting the assembly.
5. Use pulsed lavage or similar technique to remove fatty deposits from the cancellous porous structure and pat dry.
6. Apply cement to the Patellofemoral (Trochlear Implant) ensuring that cement fully covers the back side of the implant including the distal ‘tongue’.
7. Apply cement to the resected cavity and firmly pack the cement into the bone using your fingers.
8. Place the Patellofemoral (Trochlear Implant) onto the femur and impact with the Patellofemoral Impactor. Confirm that the implant is fully seated.
9. Carefully remove all excess extruded cement.
10. Hold knee joint stationary until cement has cured.

PATELLA PREPARATION

If the MAKO Patella Resection instruments are used follow the instructions below. If an alternate method of a patella resection is employed, begin at the Patella Sizing/Drill Guide instructions starting at Figure 25 and continue to the end of the procedure.

Place the leg in full extension to expose the patella and to release tension on the quadriceps.

Measure the maximum patella thickness using the Patella Calipers (degree of accuracy: +/- 0.5 mm) (Figure 20).

Estimate patella implant size by measuring the superior-inferior height of the patella articular surface. To determine proper resection thickness, refer to the table below (all dimensions are in mm).

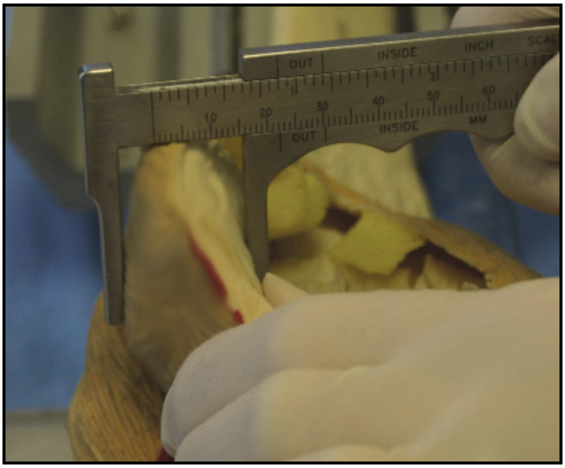


Figure 20

Size / Diameter	Patella Thickness	Resection Thickness
26	8.0	8.25
29	8.5	
32	9.0	9.25
35	9.5	
38	10.0	10.25
41	10.5	

Assemble the appropriately sized Saw Guide into the Patella Clamp to create a Saw Guide Assembly as shown in Figure 21.

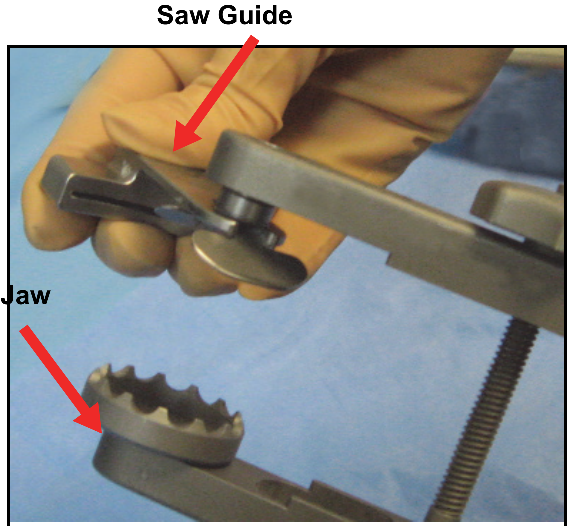


Figure 21

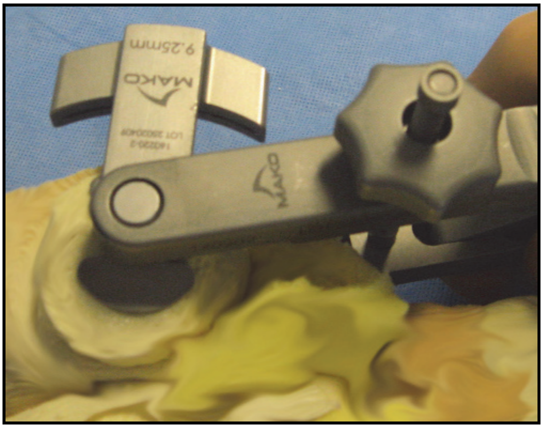


Figure 22

Align the Saw Guide cutting slot to the medial side of the patella. Position the handle approximately parallel to the tibia (Figure 22).

Engage the Saw Guide teeth onto the center of the patellar articular surface ridge and allow the wings* to guide orientation onto the medial and lateral patella facets.

Close the Saw Guide Assembly around the patella. Apply a slight clamping force, ensuring that the patellar transition zones and Saw Guide teeth provide proper alignment and that the cutting slot is comfortably accessible to the surgeon's dominant hand and the saw. The anterior side of the patella should be centered in the Clamp Jaw.

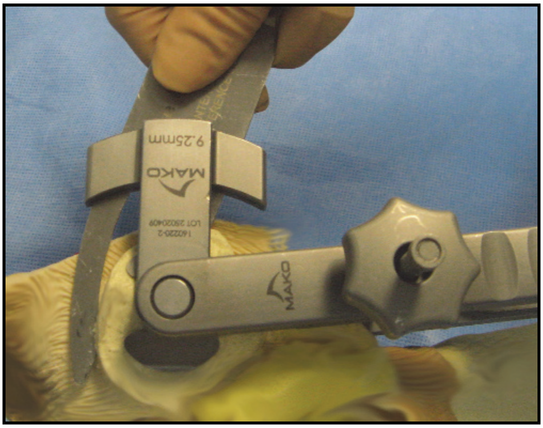


Figure 23

Use the Anterior Cut Reference Guide to verify that the start and exit of the saw blade resection is where desired (Figure 23). The proper planar resection is made when the cutting slot is aligned with the quadriceps mechanism attachments and with the medial and lateral cartilage/bone demarcations.

** For Saw Guides without wings engage the teeth onto the center of the patella articular surface ridge and apply a slight clamping force.*

Turn the knob tensioner on the Clamp to apply a clamping force on the patella. Place thumb or finger on knob tensioner to prevent possible unwinding during resection.

Insert a 25 mm x 1.27 mm (.050") saw blade through the Saw Guide and resect the articular surface of the patella (Figure 24). Ensure that the resection is flat and smooth.

Unscrew the knob tensioner and remove the Saw Guide Assembly from the patella.

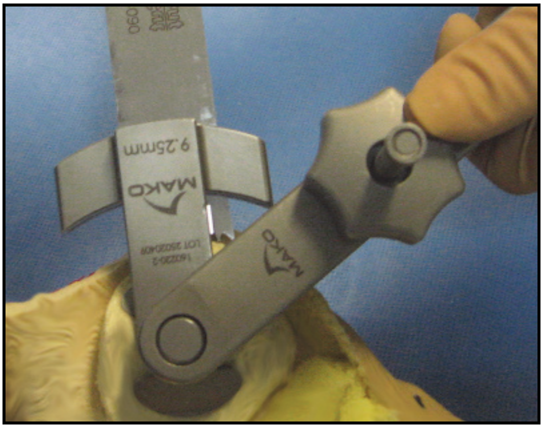


Figure 24

Using the Patella Sizing/Drill Guides select the appropriate size Patella Implant (26, 29, 32, 35, 38 or 41 mm diameter). The optimal patella size is the largest size that does not overhang the bone superior-inferiorly.

Assemble the Patella Sizing/Drill Guide into the Drill Guide Handle to create a Drill Guide Assembly, such that the selected patella size is opposite the handle teeth (Figure 25).

In the example shown, the selected 38 mm size is opposite the handle teeth, and the 41 mm size is assembled to the Drill Guide Handle.

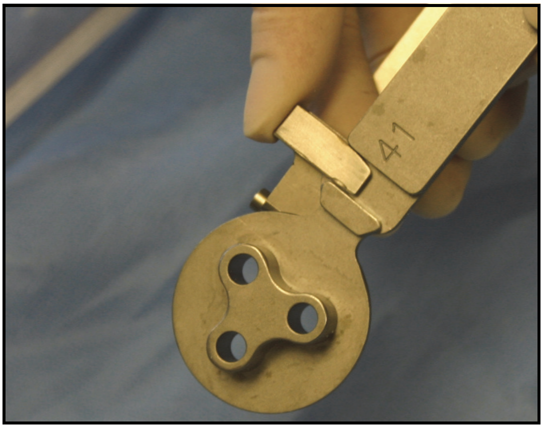


Figure 25

Clamp the Drill Guide Assembly firmly onto the patella so that the spikes fully engage and the drill guide sits flat on the bone surface. For proper patella tracking, the Patella Sizing/Drill Guide should be aligned with the former patella ridge (i.e., medialized on the patella bone). This will lateralize the remaining patella bone.

Centering the Patella Sizing/Drill Guide will medialize the remaining patella bone which can tighten the lateral quadriceps and increase the risk of lateral subluxation.

While holding the Drill Guide Assembly firmly in place, drill the three peg holes using the Patellar/Tibial Peg Drill making sure the drill stop collar contacts the top of the Patella Sizing/Drill Guide (Figure 26).

Remove the Drill Guide Assembly and any loose material from the patella.

Place the Patella Trial onto the resected patella. Use the Patella Calipers to reassess the patella thickness (Figure 27).

If the overall thickness is greater than the original patella bone thickness, consider shaving off additional patella bone.

Perform manual range of motion check to ensure proper patella tracking and patella transitioning.

Remove the Saw Guide Jaw from the Patella Clamp and insert the blue Cement Clamp Body to create a Cement Clamp Assembly (Figure 28).

Apply cement to the resected patella surface, drilled peg holes, and Patella Implant while the cement has a doughy consistency. Place the Patella component onto the resurfaced patella.

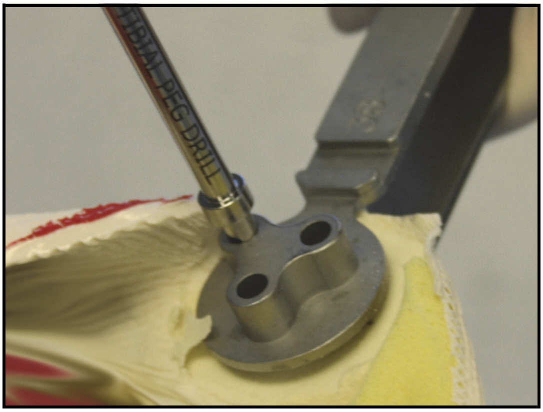


Figure 26

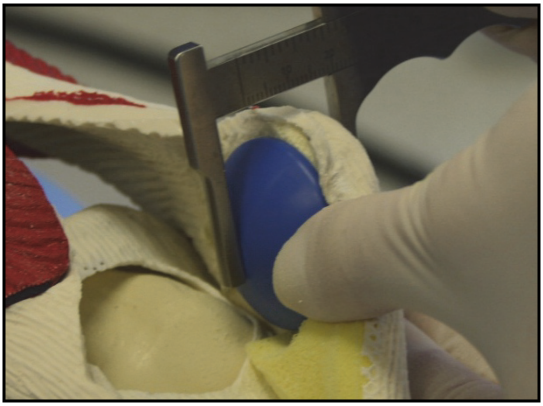


Figure 27

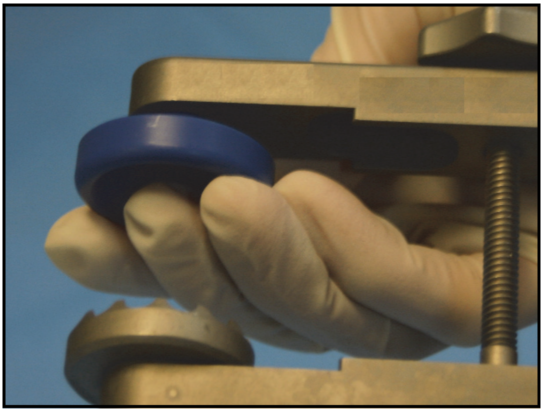


Figure 28

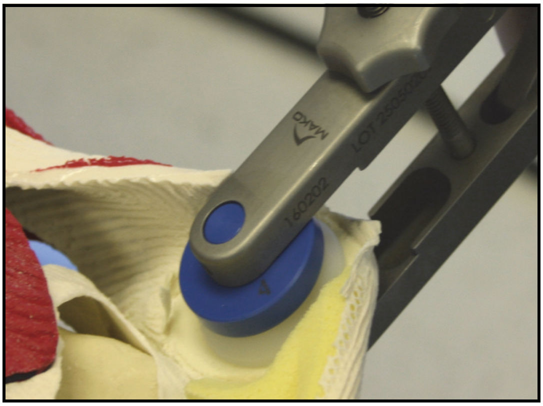


Figure 29

Fully open the jaws of the Cement Clamp Assembly and align the Cement Clamp Body onto the articular surface of the Patella Implant and Clamp Jaw teeth to the anterior surface of the patella.

Close the Cement Clamp Assembly around the patella and turn the knob tensioner to apply an adequate clamping force (Figure 29). Ensure that the Patella Implant fully seats onto the patella bone.

Remove excess cement as needed.

After the cement has sufficiently cured, loosen the knob tensioner and remove the Cement Clamp Assembly.

Perform a manual range of motion check and verification of implant fixation prior to wound closure.

RESTORIS MCK TECHNICAL DATA

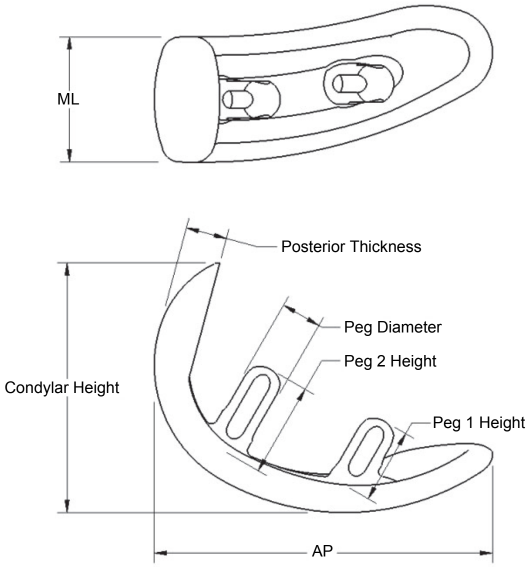
	Patellofemoral / Femoral Condyle	Tibial Inlay*	Tibial Onlay	Patella
Material	Cobalt chromium (CoCr) alloy per ASTM F75	*Tibial Inlay*:* Ultra-high molecular weight polyethylene (UHMWPE) per ASTM F648 - GUR 1050, resin type 2 - Compression molded *Radiographic Marker:* Titanium wire per ASTM F67	*Onlay Insert:* Ultra-high molecular weight polyethylene (UHMWPE) per ASTM F648 - GUR 1050, resin type 2 - Compression molded *Onlay Baseplate:* Titanium alloy per ASTM F136	Ultra-high molecular weight polyethylene (UHMWPE) per ASTM F648 - GUR 1050, resin type 2 - Compression molded
Manufacturing Process	Cast, heat-treated - Articular surface: polished - Cement-contacting surface: grit blasted	Machined from stock material	*Onlay Insert:* Machined from stock material *Onlay Baseplate:* Machined from stock material - Locking surface: satin finish - Cement-contacting surface: grit blasted	Machined from stock material
Packaging	Tyvek/Mylar inner and outer pouches	Foil inner pouch - Prior to sealing, environmental oxygen (air) is purged with inert gas - Impermeable, preventing re-entry of oxygen Tyvek/Mylar outer pouch	*Onlay Insert:* Foil inner pouch - Prior to sealing, environmental oxygen (air) is purged with inert gas - Impermeable, preventing re-entry of oxygen Tyvek/Mylar outer pouch *Onlay Baseplate:* Tyvek/Mylar inner and outer pouches	Foil inner pouch - Prior to sealing, environmental oxygen (air) is purged with inert gas - Impermeable, preventing re-entry of oxygen Tyvek/Mylar outer pouch
Sterilization	Gamma, 2.5 - 4.0 Mrad			
Shelf Life	5 years			

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

Femoral Condyle Technical Data

Size	AP	ML	Condylar Height	Distal Thickness	Posterior Thickness	Peg 1 Height	Peg 2 Height	Peg Diameter	Keel Height
1	42.0	16.0	30.9	4.0	5.8	9.00	11.0	6.5	0.0
2	45.0	17.0	33.1	4.0	6.0	9.75	12.0	6.5	0.0
3	48.0	18.0	35.4	4.0	6.2	10.50	13.0	6.5	0.5
4	51.0	19.0	37.6	4.0	6.4	11.25	14.0	6.5	1.0
5	54.0	20.0	39.9	4.0	6.6	12.00	15.0	6.5	1.5
6	57.0	21.0	42.1	4.0	6.8	12.75	16.0	6.5	2.0
7	60.0	22.0	44.4	4.0	7.0	13.50	17.0	6.5	2.5
8	63.0	23.0	46.6	4.0	7.2	14.25	18.0	6.5	3.0

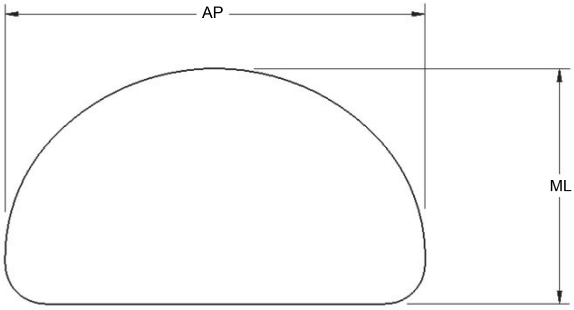
(All dimensions in mm)

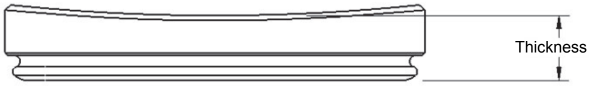

ML
Posterior Thickness
Peg Diameter
Peg 2 Height
Condylar Height
Peg 1 Height
AP

Tibial Inlay* Technical Data

Size	AP	ML	Thickness		
1	30.0	17.5	6.5	7.5	8.5
2	33.0	19.0	6.5	7.5	8.5
3	36.0	20.5	6.5	7.5	8.5
4	39.0	22.0	6.5	7.5	8.5
5	42.0	23.5	6.5	7.5	8.5
6	45.0	25.0	6.5	7.5	8.5
7	48.0	26.5	6.5	7.5	8.5

(All dimensions in mm)



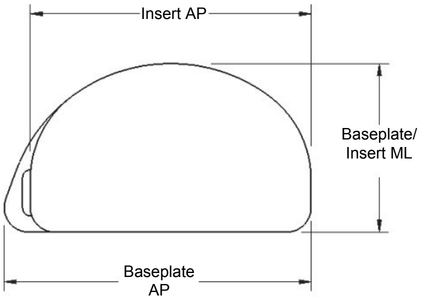


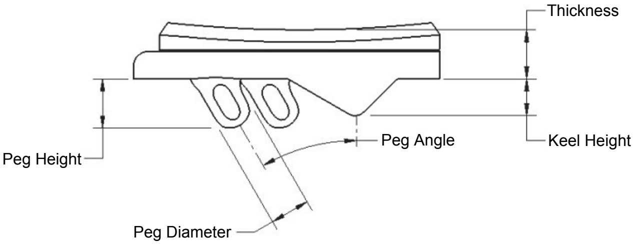
**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

Tibial Onlay Technical Data

Size	Baseplate AP	Insert AP	Baseplate/ Insert ML	Peg Height	Peg Diameter	Peg Angle (Degrees)	Keel Height	Thickness			
1	38.0	34.8	21.5	7.0	6.5	30	5.0	8.0	9.0	10.0	12.0
2	41.0	37.5	23.0	7.0	6.5	30	5.0	8.0	9.0	10.0	12.0
3	44.0	40.3	24.5	7.0	6.5	30	5.0	8.0	9.0	10.0	12.0
4	47.0	43.0	26.0	7.0	6.5	30	5.0	8.0	9.0	10.0	12.0
5	50.0	45.8	27.5	8.0	6.5	30	6.0	8.0	9.0	10.0	12.0
6	53.0	48.5	29.0	8.0	6.5	30	6.0	8.0	9.0	10.0	12.0
7	56.0	51.3	30.5	8.0	6.5	30	6.0	8.0	9.0	10.0	12.0
8	59.0	54.0	32.0	8.0	6.5	30	6.0	8.0	9.0	10.0	12.0

(All dimensions in mm unless otherwise noted)

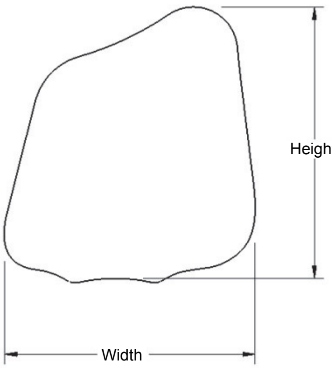

Insert AP
Baseplate/
Insert ML
Baseplate
AP

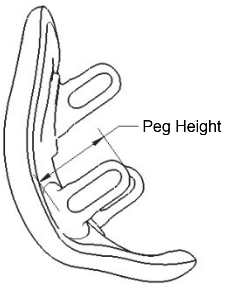

Thickness
Peg Height
Peg Angle
Keel Height
Peg Diameter

Patellofemoral Technical Data

Size	Height	Width	Peg Height	Peg Diameter
2	36.5	33.4	10.0	6.5
3	38.7	35.5	10.5	6.5
4	40.9	37.7	11.0	6.5
5	43.2	39.9	11.5	6.5
6	45.4	42.1	12.0	6.5
7	47.6	44.2	12.5	6.5
8	49.8	46.4	13.0	6.5

(All dimensions are in mm unless otherwise noted)

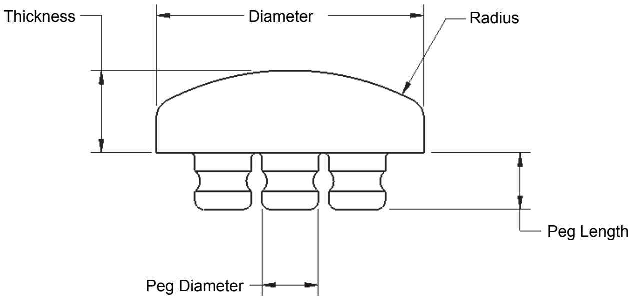


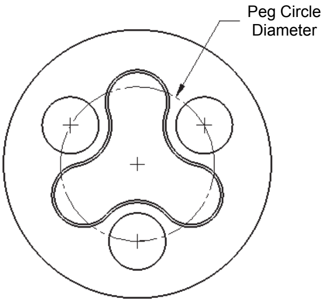


Patella Technical Data

Size	Diameter	Thickness	Radius	Peg Diameter	Peg Length	Peg Circle Diameter
26	26.0	8.0	26.0	5.5	5.5	15.0
29	29.0	8.5	26.0	5.5	5.5	15.0
32	32.0	9.0	26.0	5.5	5.5	18.0
35	35.0	9.5	26.0	5.5	5.5	18.0
38	38.0	10.0	26.0	5.5	5.5	18.0
41	41.0	10.5	26.0	5.5	5.5	18.0

(All dimensions in mm)


Thickness
Diameter
Radius
Peg Length
Peg Diameter


Peg Circle
Diameter

APPENDIX A

RESTORIS MCK Implant Planning (Medial)

- Appendix A and B describe the sequence of steps required to Pre-Operatively and Intra-Operatively plan a RESTORIS MCK Bicompartmental (‘RESTORIS MCK Bi-Comp.’)
- These Appendices can also be used to plan the components of a ‘RESTORIS MCK PF’ and a ‘RESTORIS MCK UKA’. Although the steps are the same, the screen shot pictures will not be representative for a single compartment.
- If only performing an RESTORIS MCK PF or an RESTORIS MCK UKA, it is recommended to plan for an RESTORIS MCK Bi-Comp to characterize size and fit of each component.
    - For an RESTORIS MCK PF, select the RESTORIS MCK PF from the Implant System menu. Otherwise, Tibia Registration and Joint Balancing will be required.
    - For an RESTORIS MCK UKA, exit the RESTORIS MCK Bi-Comp and select the RESTORIS MCK UKA from the Implant System menu. Otherwise, Bicompartmental Registration will be required. If this is acceptable, remain in RESTORIS MCK Bi-Comp and ignore the RESTORIS MCK PF.
- Each transverse, coronal and sagittal window in the following recommended technique panel is labeled with a 1, 2, or 3 respectively. The instructions in the left column are also labeled with a 1, 2, or 3, to correspond to the applicable window panel.

For each component, required views in each window panel (crosshair) ⌖ are set by choosing the ‘primary’ or applicable ‘verify’ option for each component. The remaining instructions are only applicable if those views are not altered.

RESTORIS MCK Implant Planning Pre-Operative Sequence

- This is the recommended procedural Sequence
- This sequence was designed to limit the number of times switching between components
- The sequence can be performed in a different order, but additional component adjustment may be necessary to avoid intercomponent impingement

Tibial

- Drag from Default location to approximate location
- Size (repeat above step if size changed)
- Fit (rotate and translate)
- Verify fit

Bicompartmental

- Drag from Default location to approximate location
- Size (repeat above step if size changed); this step aids in initial Patellofemoral and Femoral sizing

Patellofemoral (Trochlear)

- Drag from Default location to approximate location (if necessary)
- Verify size (re-drag size if changed)
- Fit (rotate and translate)
- Verify fit

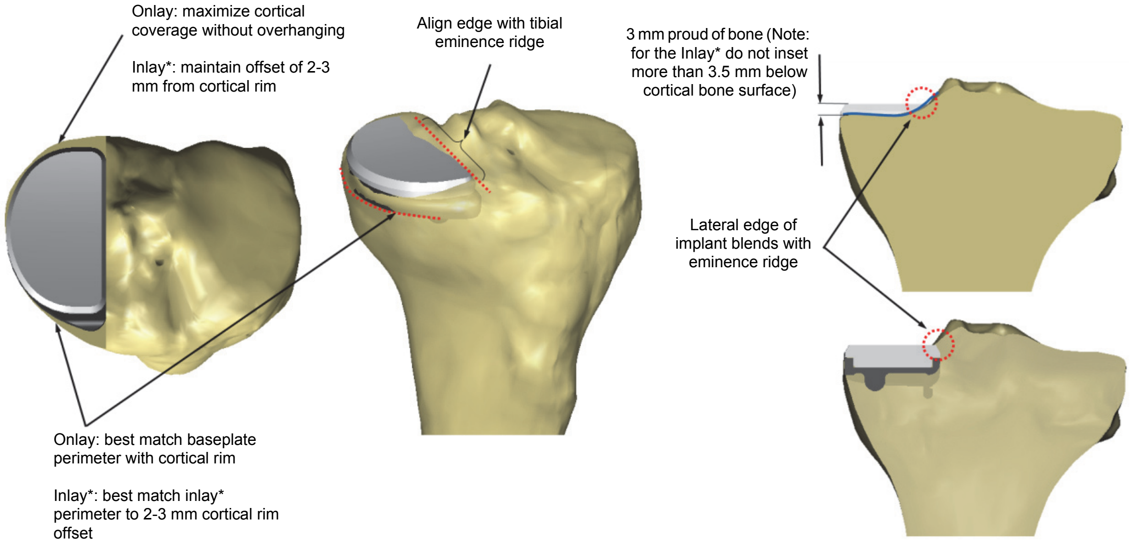
Femoral

- Drag from Default location to approximate location (if necessary)
- Verify size (re-drag size if changed)
- Fit (rotate and translate)
- Verify fit

Implant Planning Abbreviations

- AP – Anterior-Posterior
- ML – Medial-Lateral
- SI – Superior-Inferior (same as Proximal-Distal)
- V/V – Varus-Vargus
- F/E– Flexion-Extension
- I/E– Internal-External
- PFJ – Patellofemoral Joint procedure
- UKA – Unicondylar Knee Arthroplasty procedure
- PF – Patellofemoral (Trochlear) component

RESTORIS MCK Tibial Component Pre-Operative Planning: Summary



Onlay: maximize cortical coverage without overhanging

Inlay*: maintain offset of 2-3 mm from cortical rim

Align edge with tibial eminence ridge

3 mm proud of bone (Note: for the Inlay* do not inset more than 3.5 mm below cortical bone surface)

Lateral edge of implant blends with eminence ridge

Onlay: best match baseplate perimeter with cortical rim

Inlay*: best match inlay* perimeter to 2-3 mm cortical rim offset

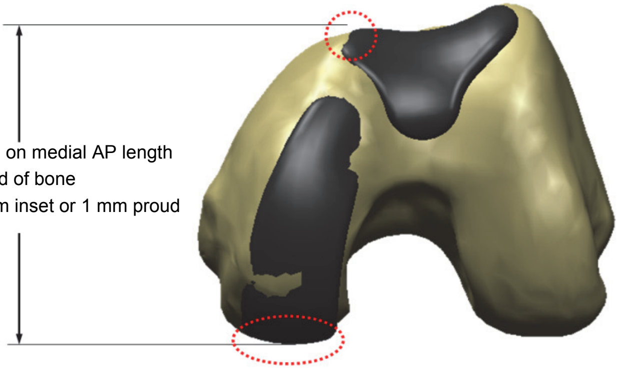
Set implant in Primary view and scroll through the slices or use the Verify 1 and Verify 2 preset views to verify planning criteria.

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

RESTORIS MCK Bicompartmental Pre-Operative Planning: Summary

The Bicompartmental planning step is used to set initial size of the PF (trochlear) and Femoral Condyle components

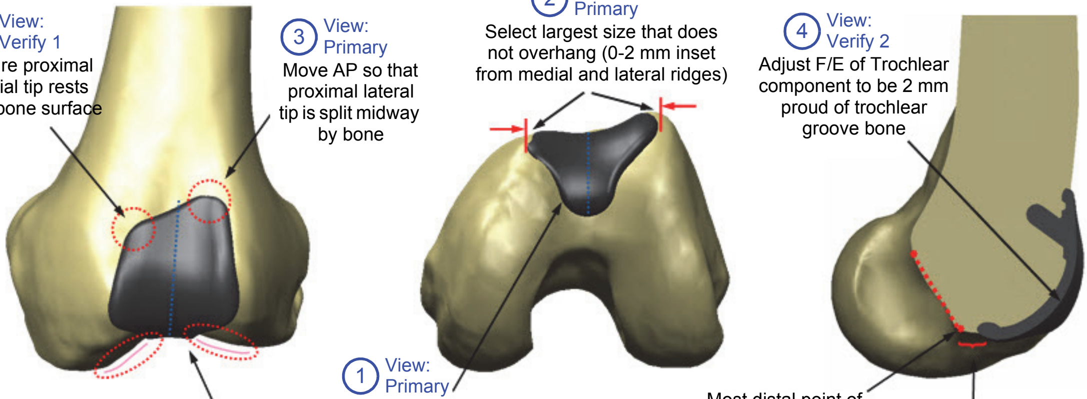
- Changing sizes changes the size of both components
- Adjusting position simultaneously changes position of both components



Bicompartmental size based on medial AP length

- Anterior: PF is 1 mm proud of bone
- Posterior: Femoral is 2 mm inset or 1 mm proud

Patellofemoral (Trochlear) Pre-Operative Planning: Summary



⑦ View: Verify 1
Ensure proximal medial tip rests on/in bone surface

③ View: Primary
Move AP so that proximal lateral tip is split midway by bone

② View: Primary
Select largest size that does not overhang (0-2 mm inset from medial and lateral ridges)

④ View: Verify 2
Adjust F/E of Trochlear component to be 2 mm proud of trochlear groove bone

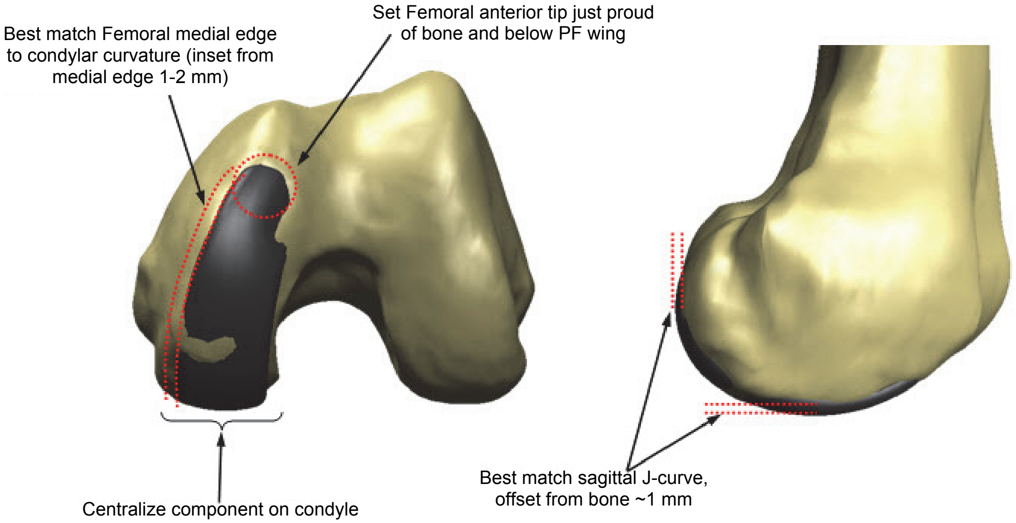
Set PF wings 2 mm proud of bone
⑥ View: Primary

① View: Primary
Set Trochlear I/E rotation to 0-4° internal (acceptable for implant to be recessed into lateral cortex)

Most distal point of intercondylar groove

Ensure distal tip is anterior to Blumensaat's line
⑤ View: Verify 2

RESTORIS MCK Femoral Component Pre-Operative Planning: Summary

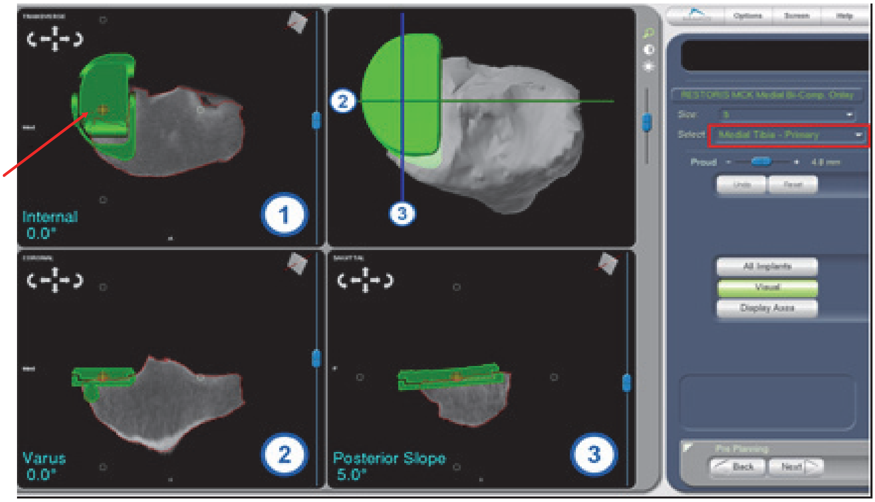

Best match Femoral medial edge to condylar curvature (inset from medial edge 1-2 mm)
Set Femoral anterior tip just proud of bone and below PF wing
Centralize component on condyle
Best match sagittal J-curve, offset from bone ~1 mm

Set implant in Primary view and verify intercomponent gap in Verify 1

Tibial Component

Pre-Operative Tibial Planning – Default Position

- Component is imported in Default location
- Size 5 is Default size
- Select 'Medial Tibia-Primary'
  - Crosshair automatically positioned at implant center:
  - ① 3.5 mm from top
  - ② Center of medial peg
  - ③ ML midplane
  - 3D view set to Transverse (Proximal)



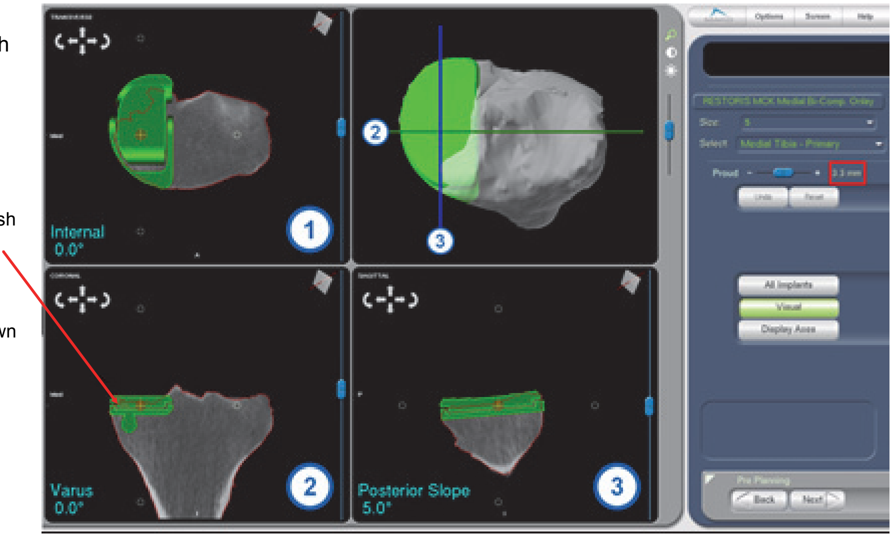
Internal
0.0°
1
2
3
Varus
0.0°
2
Posterior Slope
5.0°
3
Options
Screen
Help
RESTORIS MCK Medial Bi-Comp. Onlay
Size
5
Select
Medial Tibia - Primary
Proud
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
Back
Next

Pre-Operative Tibial Planning – Drag

① Drag and drop component into a rough AP and ML position

③ Drag component to ~3 mm proud

- Onlay Visual gap
  - Gap created to distinguish between Baseplate & Insert
  - Note: gap created by removing material from Insert so Baseplate shown corresponds to actual geometry



Internal
0.0°
1
2
3
Varus
0.0°
2
Posterior Slope
5.0°
3
Options
Screen
Help
RESTORIS MCK Medial Bi-Comp. Onlay
Size
5
Select
Medial Tibia - Primary
Proud
Undo
Reset
All Implants
Visual
Display Axes
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Back
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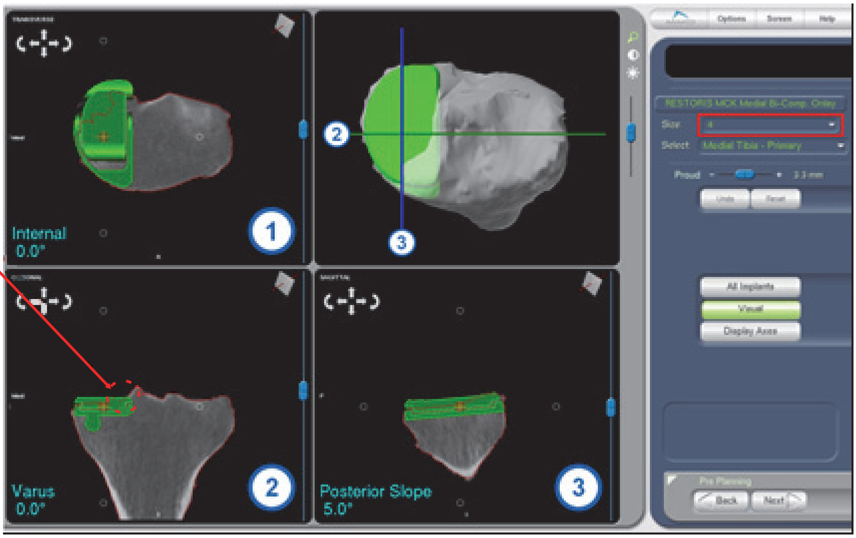
Pre-Operative Tibial Planning – Size

① Determine Tibial Component size:

② Onlay
  - Ideal size is largest component that will not overhang AP, ML, and not intrude into tibial intercondylar eminence

③ Inlay*
  - Ideal size is largest component that is 2-3 mm from cortical rim and not intrude into tibial intercondylar eminence


RESTORIS MCK Medial Bi-Comp. Onlay
Size: 4
Select: Medial Tibia - Primary
Proud 3.3 mm

TRANSVERSE
Internal
0.0°
1
2
3
CORONAL
Varus
0.0°
2
SAGITTAL
Posterior Slope
5.0°
3
Options
Screen
Help
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
Back
Next

Tibial Planning – Recommended Positioning Limits

Tibial Onlay

① 5° internal ↔ 5° external
AP: on cortical rim

② 0° varus ↔ 1.5° varus
ML: on cortical rim

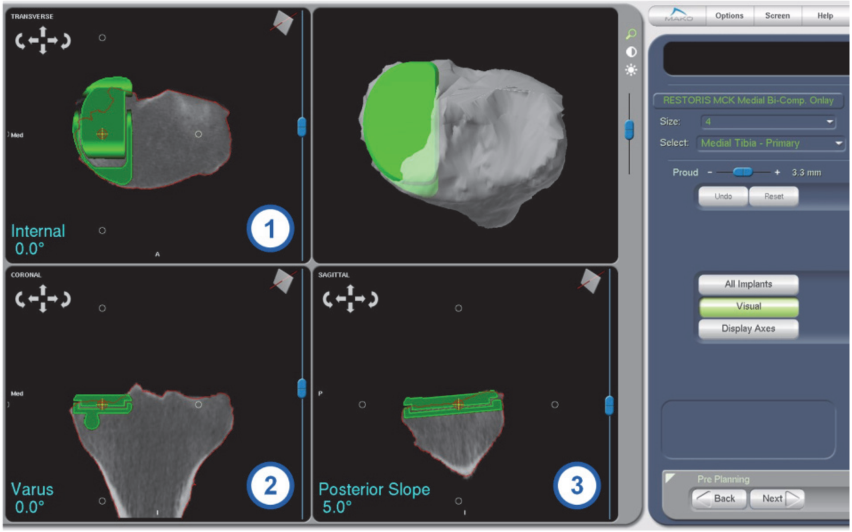
③ 3° slope ↔ 7° slope
SI: 2.5-3.5 mm proud

Tibial Inlay*

① 5° internal ↔ 5° external
AP: 2-3 mm from cortical rim

② 1° varus ↔ 3° varus
ML: 2-3 mm from cortical rim

③ 3° slope ↔ 7° slope
SI: 2.5-3.5 mm proud


RESTORIS MCK Medial Bi-Comp. Onlay
Size: 4
Select: Medial Tibia - Primary
Proud 3.3 mm

TRANSVERSE
Med
Internal
0.0°
1
CORONAL
Med
Varus
0.0°
2
SAGITTAL
P
Posterior Slope
5.0°
3
MAKO
Options
Screen
Help
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
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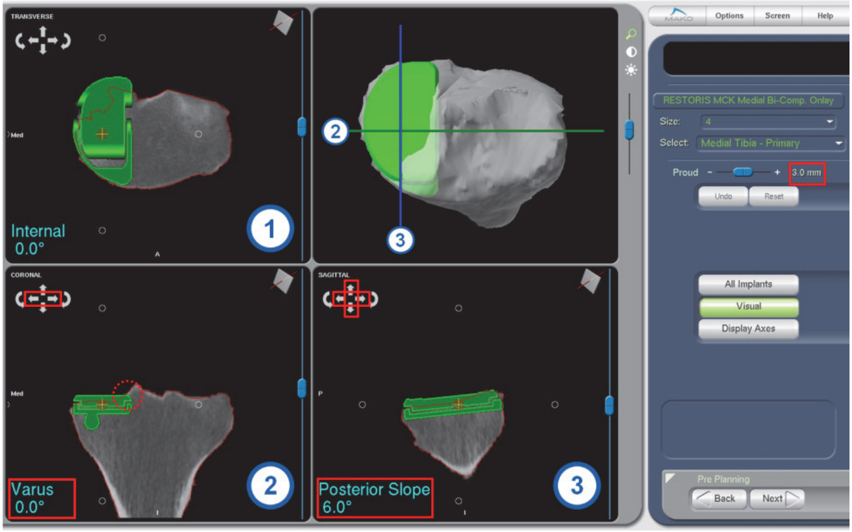
Next

RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.

Pre-Operative Tibial Planning – Fit

③ Adjust posterior slope to be slightly less than patient tibial bone slope
  - Removal of meniscus and excessive slope can stress the ACL
- Adjust proudness to 3 mm
- Adjust AP position:
  - Onlay: avoid overhang
  - Inlay*: 2-3 mm inset from cortical rim

② Adjust V/V:
  - Onlay: stay within positioning limits
  - Inlay*: adjust to be slightly less than tibial varus slope
- Adjust ML to avoid intrusion into the tibial eminence and:
  - Onlay: avoid overhang
  - Inlay*: 2-3 mm inset from cortical rim



Internal 0.0°

Varus 0.0°

Posterior Slope 6.0°

RESTORIS MCK Medial Bi-Comp. Onlay

Size: 4

Select: Medial Tibia - Primary

Proud 3.0 mm

TRANSVERSE
Med
A
1
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3
CORONAL
SAGITTAL
P
MAKO
Options
Screen
Help
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
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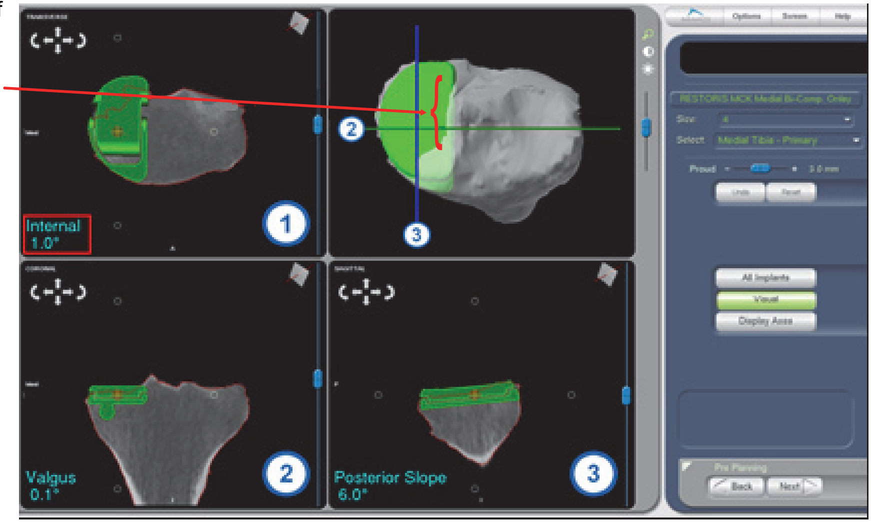
Next

Pre-Operative Tibial Planning – Fit

① Adjust I/E to align edge of component with tibial intercondylar eminence edge and to avoid PCL notch
  - Note: ignore anterior bone when assessing I/E rotation



Internal 1.0°

Valgus 0.1°

Posterior Slope 6.0°

1
2
3
Options
Screen
Help
All Implants
Visual
Display Axes
Pre Planning
Back
Next

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

Pre-Operative Tibial Planning – Verify Fit

- Select 'Medial Tibia-Verify 1'

③ Re-adjust proudness to 3 mm, if necessary

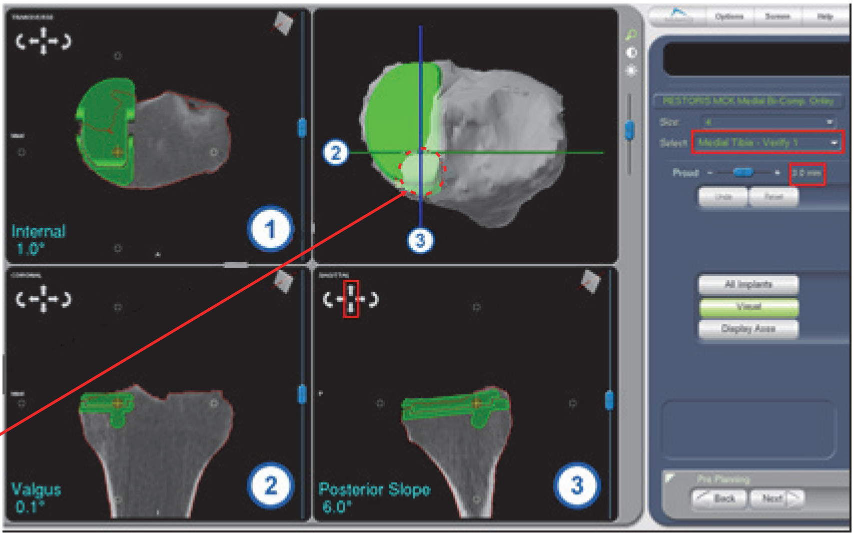
② Onlay

③ - Verify implant rests on cortical rim and does not interfere with eminence

② Inlay*

③ - Verify implant is 2-3 mm from cortical rim (not including osteophytes)
  - To maintain subchondral bone plate, do not inset ≥3.5 mm below cortical surface

- Note: some bone might be proud at anterior tip


TRANSVERSE
Internal
1.0°
1
2
3
CORONAL
Valgus
0.1°
2
SAGITTAL
Posterior Slope
6.0°
3
Options
Screen
Help
RESTORIS MCK Medial Bi-Comp. Onlay
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
Back
Next

Size: 4
Select: Medial Tibia - Verify 1
Proud 3.0 mm

Pre-Operative Tibial Planning – Verify Fit

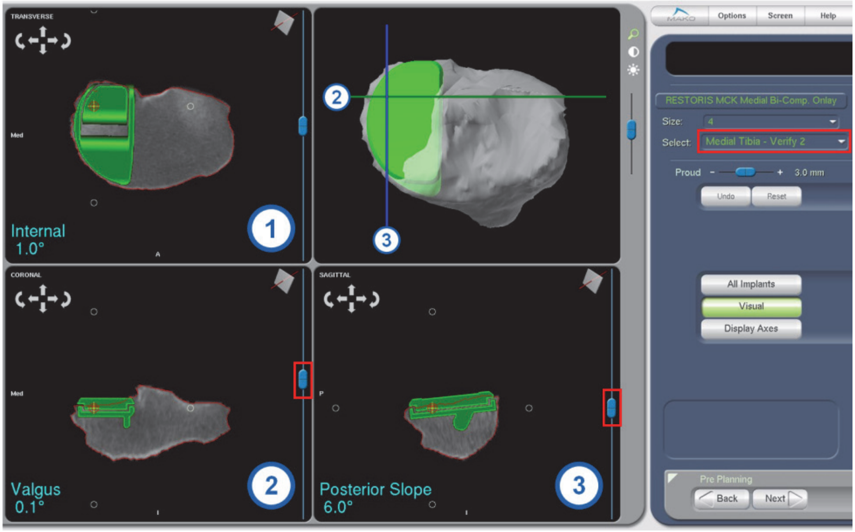
- Select 'Medial Tibia-Verify 2'

② Onlay

③ - Verify implant does not overhang AP & ML
  - Scroll through slices as necessary to ensure proper fit

② Inlay*

③ - Verify implant is 2-3 mm from cortical rim (not including osteophytes)
  - Scroll through slices as necessary to ensure proper fit


TRANSVERSE
Med
A
Internal
1.0°
1
2
3
CORONAL
Med
Valgus
0.1°
2
SAGITTAL
P
Posterior Slope
6.0°
3
MAKO
Options
Screen
Help
RESTORIS MCK Medial Bi-Comp. Onlay
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
Back
Next

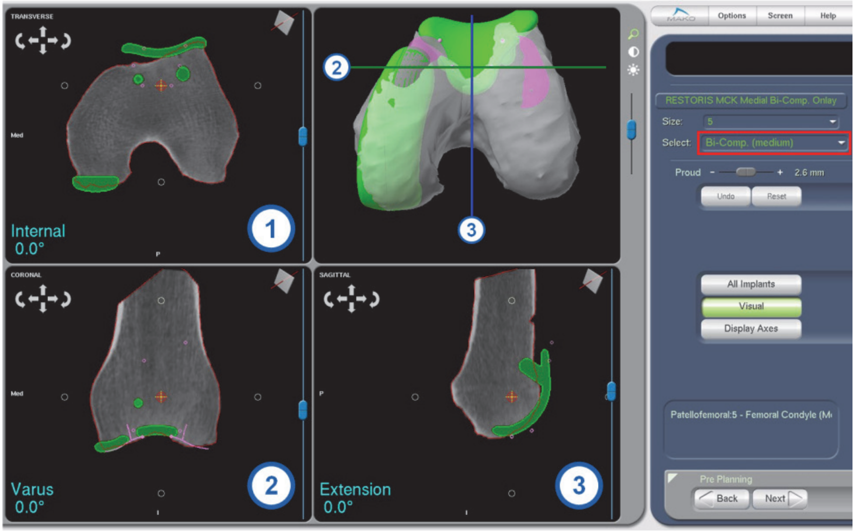
Size: 4
Select: Medial Tibia - Verify 2
Proud 3.0 mm

RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.

Bicompartmental Component

Pre-Operative Bicompartmental Planning – Default Position

- Component is imported in Default location
- Size 5 is Default size
- Select 'Bi-Comp (medium)'
  - ⌖ Crosshair automatically positioned through largest AP section:
  - ① Largest AP length (Upside-down 'Frowny Face')
  - ② Patella transition (distal tongue of PF)
  - ③ ML center of PF ('Fish Hook')
  - ◆ 3D view set to Transverse (Distal)

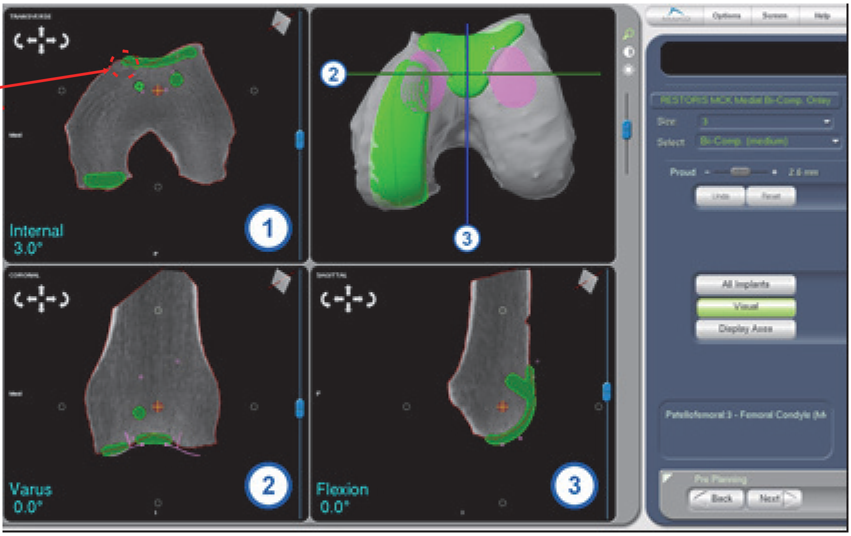

TRANSVERSE
CORONAL
SAGITTAL
Med
P
Internal
0.0°
Varus
0.0°
Extension
0.0°
1
2
3
Options
Screen
Help
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
Back
Next

RESTORIS MCK Medial Bi-Comp. Onlay
Size: 5
Select: Bi-Comp. (medium)
Proud 2.6 mm
Patellofemoral:5 - Femoral Condyle (M

Pre-Operative Bicompartmental Planning – Drag

② Drag Bicompartmental so that medial side of PF is approximately 1 mm proud of red bone surface

③ Drag Bicompartmental so that PF tongue is split midway by red bone surface


Internal
3.0°
Varus
0.0°
Flexion
0.0°
1
2
3
Options
Screen
Help
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
Back
Next

RESTORIS MCK Medial Bi-Comp. Onlay
Size: 3
Select: Bi-Comp. (medium)
Proud 2.6 mm
Patellofemoral:3 - Femoral Condyle (M

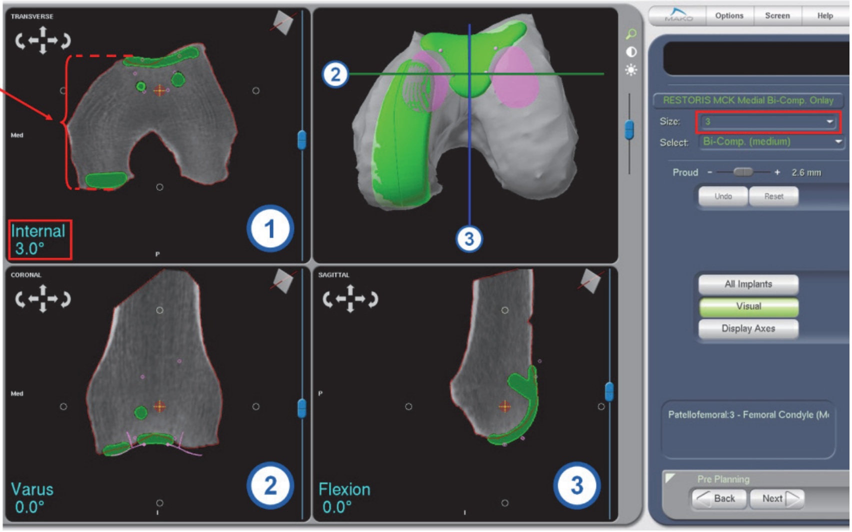
Pre-Operative Bicompartmental Planning – Size

① Bicompartmental sizing:

- Based on AP medial bone length
- Ideal Bicomp size:
  - Anterior medial PF:1 mm proud of bone
  - Posterior Condyle:2 mm inset or 1 mm proud
- If Posterior Condyle

  >2 mm inset → upsize

  >1 mm proud → downsize
- Note: some internal rotation might be required to assess size
- If size changed, re-drag component to correct location


TRANSVERSE
Med
P
Internal
3.0°
1
2
3
CORONAL
Med
I
Varus
0.0°
2
SAGITTAL
P
I
Flexion
0.0°
3
MAKO
Options
Screen
Help
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
Back
Next

RESTORIS MCK Medial Bi-Comp. Onlay

Size: 3

Select: Bi-Comp. (medium)

Proud 2.6 mm

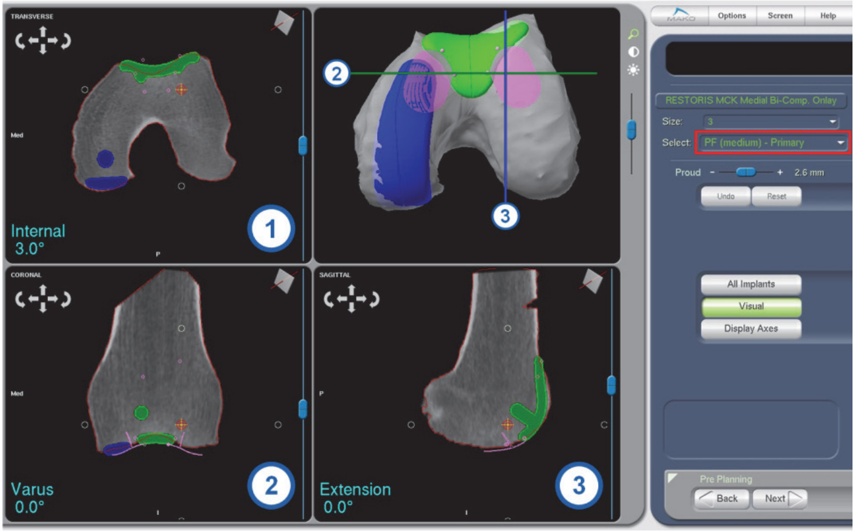
Patellofemoral:3 - Femoral Condyle (M

Patellofemoral (Trochlear) Component

Pre-Operative Patellofemoral Planning – Default Position

- Size and position are based on Bicompartmental planning
- Select 'PF-Primary'

⌖ Crosshair automatically positioned:
① Widest section of PF ('Mad Face')
② Patella transition (distal tongue of PF)
③ Proximal lateral tip (solid lateral sphere)
3D view set to Transverse (Distal)


TRANSVERSE
Med
P
Internal
3.0°
1
2
3
CORONAL
Med
Varus
0.0°
2
SAGITTAL
P
Extension
0.0°
3
Options
Screen
Help
All Implants
Visual
Display Axes
Undo
Reset
Pre Planning
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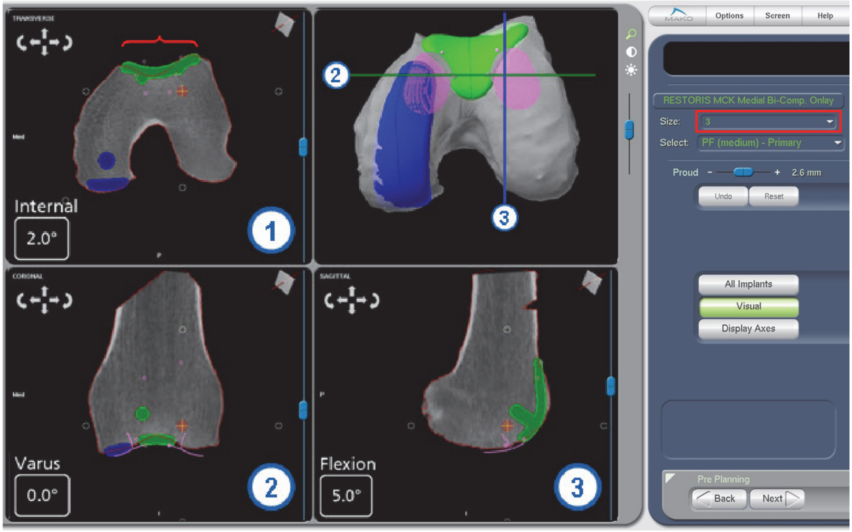
Next

RESTORIS MCK Medial Bi-Comp. Onlay
Size: 3
Select: PF (medium) - Primary
Proud 2.6 mm

Pre-Operative Patellofemoral Planning – Verify Size

① Verify PF size:
- Ideal PF size is the largest that does not overhang the bone ridges (no more than 2 mm inset on either side) ensuring it does not interfere with the ACL (not including osteophytes)
- If size changed, re-select 'PF-Primary' and move to correct location


TRANSVERSE
Med
P
Internal
2.0°
1
2
3
CORONAL
Med
Varus
0.0°
2
SAGITTAL
P
Flexion
5.0°
3
Options
Screen
Help
All Implants
Visual
Display Axes
Undo
Reset
Pre Planning
Back
Next

RESTORIS MCK Medial Bi-Comp. Onlay
Size: 3
Select: PF (medium) - Primary
Proud 2.6 mm

Patellofemoral (Trochlear) - Recommended Positioning Limits

Patellofemoral (Trochlear)

① 4° internal ↔ 0° external

AP: ~2 mm proud of bone at the trochlear groove

NOTE: Every degree of internal rotation medializes the trochlear groove ~0.5 mm and raises the patella jump height ~0.3 mm

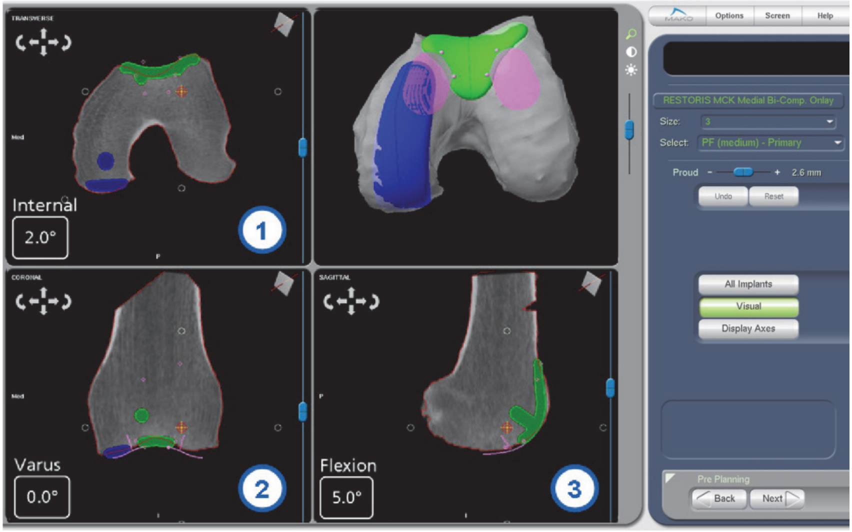
② 3° varus ↔ 2° valgus

ML: centered on notch

NOTE: Every degree of V/V rotation translates the trochlear groove entrance by ~0.6 mm

② 5° flexion ↔ 5° extension

SI: bone line splits implant



Internal 2.0°

Varus 0.0°

Flexion 5.0°

RESTORIS MCK Medial Bi-Comp. Onlay

Size: 3

Select: PF (medium) - Primary

Proud 2.6 mm

TRANSVERSE
CORONAL
SAGITTAL
Med
P
1
2
3
MAKO
Options
Screen
Help
-
+
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
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Next

Pre-Operative Patellofemoral Planning – Fit

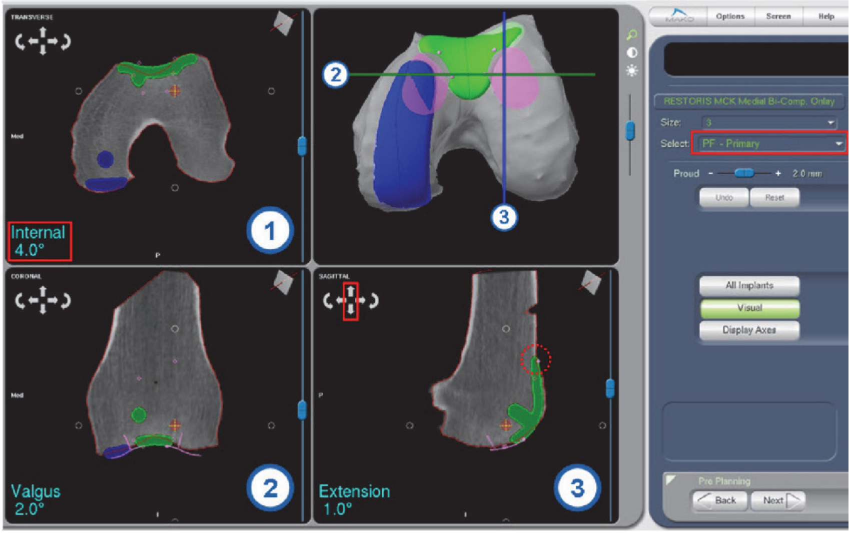
- Select 'PF-Primary'

① Fit anterior shape:

- If desired, adjust I/E to roughly match the anatomy. If Internal rotation is used ensure that the lateral PF ridge is not proud of bone.
- For lateral dysplasia, try to maintain 1 mm of lateral proudness without going into external rotation

③ Fit proximal lateral tip:

- Move AP so that the proximal lateral tip of PF is split midway by the bone surface



Internal 4.0°

Valgus 2.0°

Extension 1.0°

RESTORIS MCK Medial Bi-Comp. Onlay

Size: 3

Select: PF - Primary

Proud 2.0 mm

TRANSVERSE
CORONAL
SAGITTAL
Med
P
1
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3
MAKO
Options
Screen
Help
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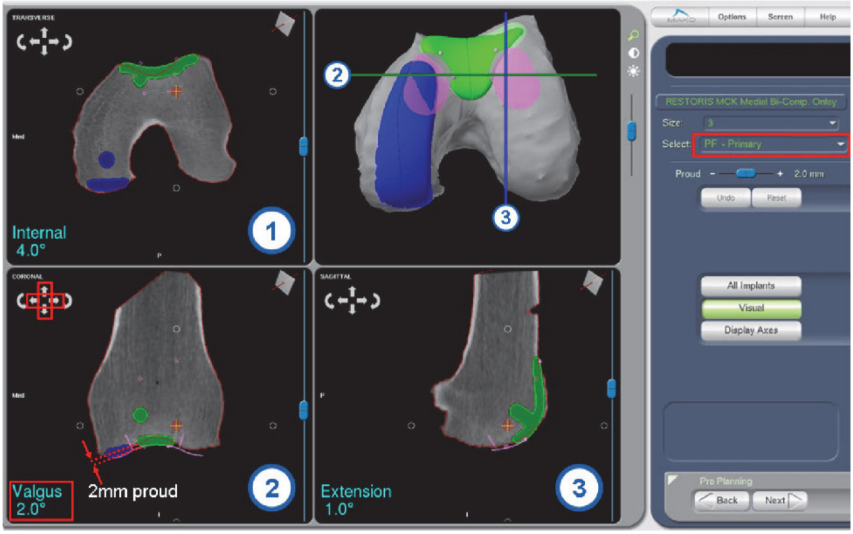
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
Back
Next

Pre-Operative Patellofemoral Planning – Fit

- Select ‘PF-Primary’

② Fit distal tongue:
  - Adjust V/V and ML to best match patellar transition zones shape to bone shape
  - Adjust SI so patellar transition zones are 2 mm proud of bone surface



RESTORIS MCK Medial Bi-Comp. Onlay

Size: 3

Select: PF - Primary

Proud 2.0 mm

TRANSVERSE
Med
Internal
4.0°
P
1
2
3
CORONAL
Valgus
2.0°
2mm proud
SAGITTAL
Extension
1.0°
Options
Screen
Help
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
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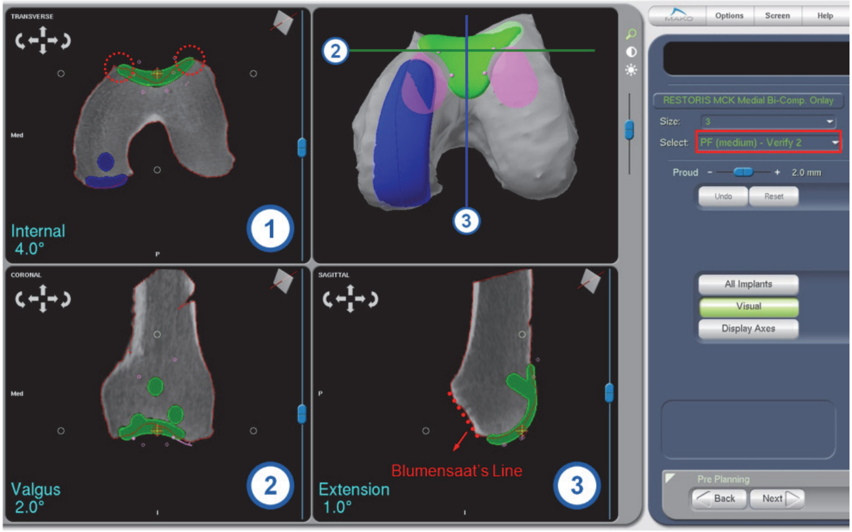
Next

Pre-Operative Patellofemoral Planning – Verify Fit

- Select ‘PF-Verify 2’

③ Verify ACL notch:
  - Adjust F/E so that the trochlear groove of the implant is ~2 mm proud of bone
  - Verify that distal tongue does not violate the intercondylar notch and cause ACL impingement. PF distal tip should be anterior to Blumensaat’s line



RESTORIS MCK Medial Bi-Comp. Onlay

Size: 3

Select: PF (medium) - Verify 2

Proud 2.0 mm

TRANSVERSE
Med
Internal
4.0°
P
1
2
3
CORONAL
Valgus
2.0°
SAGITTAL
Blumensaat’s Line
Extension
1.0°
Options
Screen
Help
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
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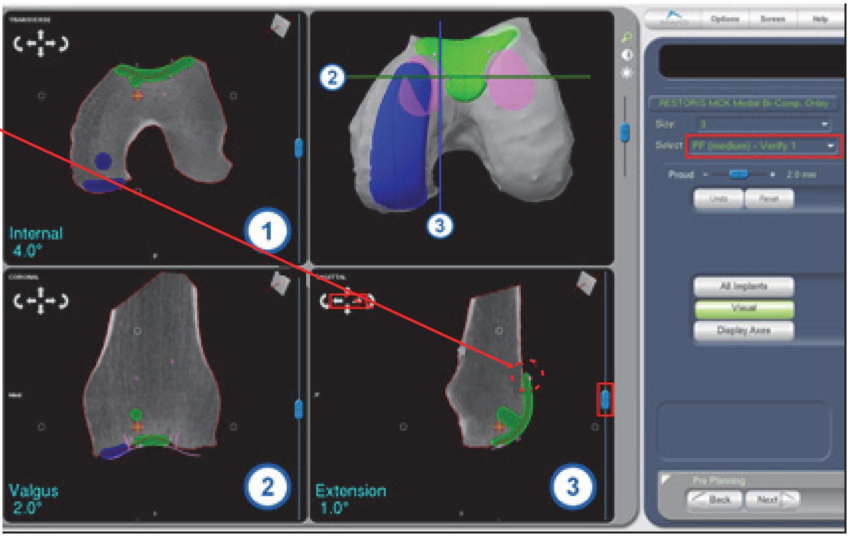
Pre-Operative Patellofemoral Planning – Verify Fit

- Select ‘PF-Verify 1’

③ Verify fit of proximal medial tip:
  - Verify medial tip of PF rests in or on red bone surface (does not need to be split by red bone surface)
  - If the medial tip rests off bone, translate PF posterior to rest on bone surface

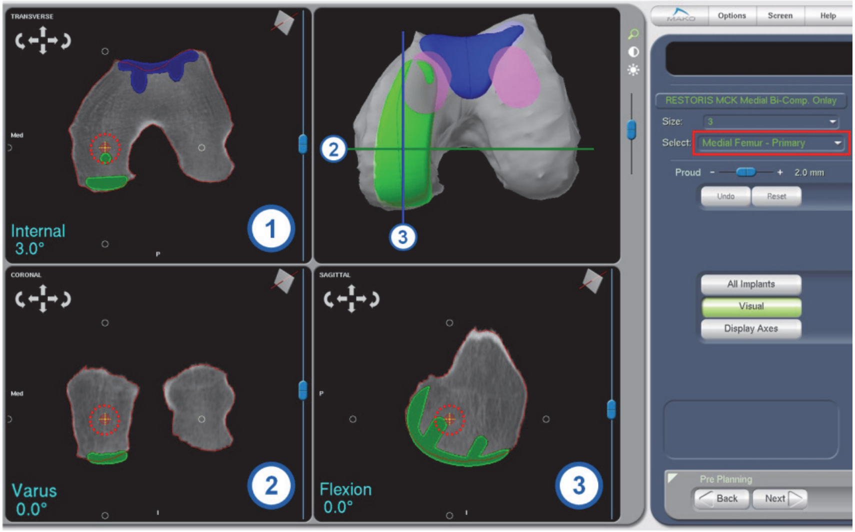

Internal
4.0°
Valgus
2.0°
Extension
1.0°
1
2
3
2
3
Options
Screen
Help
RESTORIS MCK Medial Bi-Comp. Only
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
Back
Next

Size: 3
Select: PF (medium) - Verify 1
Proud 2.0 mm

Femoral Component

Pre-Operative Femoral Planning – Default Position

- Size and position are based on Bicompartmental planning
- Select 'Medial Femur-Primary'
  - ⌖ Crosshair automatically positioned at flexion facet center (near posterior peg tip)
  - ◩ 3D view set to Transverse (Distal)


TRANSVERSE
Med
P
Internal
3.0°
1
2
3
CORONAL
Med
Varus
0.0°
2
SAGITTAL
P
Flexion
0.0°
3
Options
Screen
Help
RESTORIS MCK Medial Bi-Comp. Onlay
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
Back
Next

Size: 3
Select: Medial Femur - Primary
Proud - + 2.0 mm

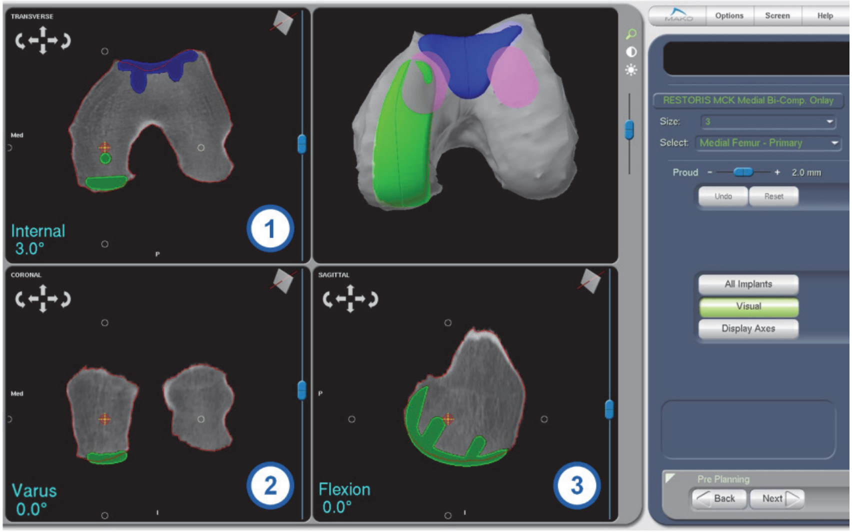
Femoral Planning – Recommended Positioning Limits

Femoral Condyle

① 5° internal ↔ 5° external
AP: 1 mm proud of bone

② 3° varus ↔ 3° valgus
ML: centered on condyle

③ 5° flexion ↔ 5° extension
SI: 1 mm proud of bone


TRANSVERSE
Med
P
Internal
3.0°
1
CORONAL
Med
Varus
0.0°
2
SAGITTAL
P
Flexion
0.0°
3
Options
Screen
Help
RESTORIS MCK Medial Bi-Comp. Onlay
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
Back
Next

Size: 3
Select: Medial Femur - Primary
Proud - + 2.0 mm

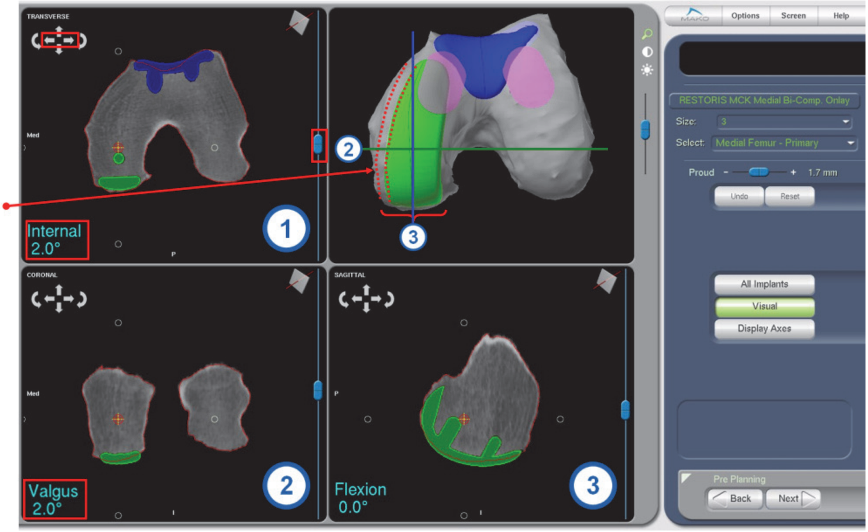
Pre-Operative Femoral Planning – Fit

① Match medial condylar curvature of bone:

- Adjust I/E to match condylar curvature (excluding osteophytes)
- Adjust ML to centralize condyle and to be 1-2 mm inset from medial edge

② Adjust V/V to match PF component

- Do not try to match component shape with arthritic bone shape using V/V


TRANSVERSE
CORONAL
SAGITTAL
Med
P
1
2
3
Options
Screen
Help
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
Back
Next

Internal 2.0°

Valgus 2.0°

Flexion 0.0°

RESTORIS MCK Medial Bi-Comp. Onlay

Size: 3

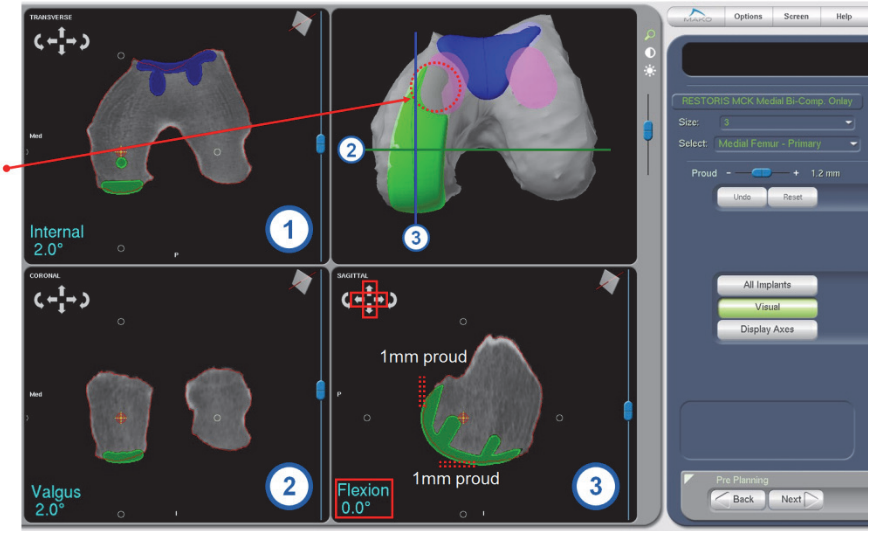
Select: Medial Femur - Primary

Proud 1.7 mm

Pre-Operative Femoral Planning – Fit

③ Match 'J-curve':

- Adjust AP, SI, & F/E to match bone J-curve and to be 1 mm proud of bone
- Adjust F/E as necessary to ensure anterior tip is not inset into bone and not protruding through PF transition zone


TRANSVERSE
CORONAL
SAGITTAL
Med
P
1
2
3
1mm proud
1mm proud
Options
Screen
Help
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
Back
Next

Internal 2.0°

Valgus 2.0°

Flexion 0.0°

RESTORIS MCK Medial Bi-Comp. Onlay

Size: 3

Select: Medial Femur - Primary

Proud 1.2 mm

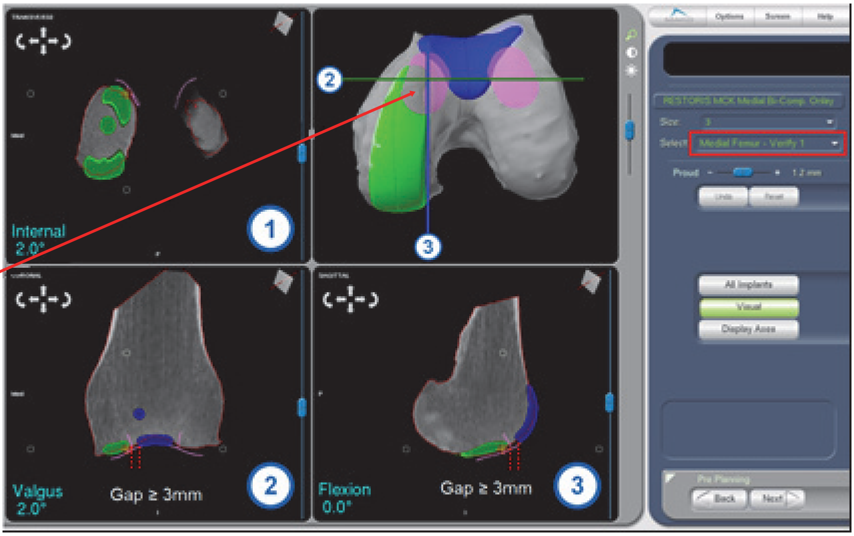
Pre-Operative Femoral Planning – Verify Fit

- Select ‘Medial Femur – Verify 1’

② Verify intercomponent gap is ≥3 mm and the Femoral does not protrude through patellar transition zone

③ Verify intercomponent gap is ≥3 mm and the Femoral does not protrude through patellar transition zone

  - Anterior tip of Femoral should be slightly proud of bone
  - For a UKA, the Femoral should not be proud of the cartilage


Internal
2.0°
①
②
③
Valgus
2.0°
Gap ≥ 3mm
②
Flexion
0.0°
Gap ≥ 3mm
③
Options
Screen
Help
RESTORIS MCK Medial Bi-Comp. Onlay
Size:
Select:
Medial Femur - Verify 1
Proud
1.2 mm
Undo
Reset
All Implants
Visual
Display Axes
Pre Planning
Back
Next

APPENDIX B

RESTORIS MCK Implant Planning Intra-Operative Sequence

- Verify the Pre-Operative plan prior to Intra-Operative planning
- The Bicompartmental step in Pre-Operative planning is only used to establish initial component sizing, therefore is not needed for Intra-Operative planning

Joint Balancing (Pose Capture)

- Remove osteophytes and apply moment at ankle
- 5° - 10° (Extension gap balancing)
- 45° (Mid flexion gap balancing)
- 95° (Flexion gap balancing)
- 100° - 120° (Maximum flexion)

Tibial

- Verify size and fit using same steps as Pre-Operative Planning

Patellofemoral (Trochlear)

- Map bone and cartilage
- Adjust placement and best match proximal lateral tip, trochlear groove, and patella transition
- Verify fit

Femoral

- Map cartilage at anterior tip
- Best match to Tibial tracking point
- Adjust placement to desired gap balancing graph profile
- Verify fit

Intra-Operative Planning

Joint Balancing (Pose Capture)

- Prior to Joint Balancing (Pose Capture)
    - Ensure osteophytes have been removed

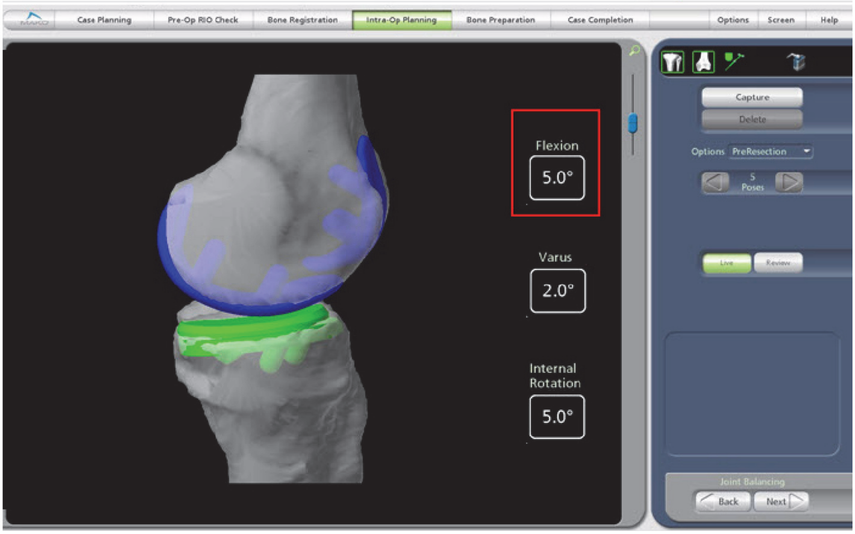
- During Joint Balancing (Pose Capture)
    - Ensure VALGUS moment is applied to tibia at each pose

- Recommended Pose Captures for Joint Balancing*
    - 5˚-10˚ (Extension gap balancing)
    - 45˚ (Mid-flexion gap balancing)
    - 90˚ (Flexion gap balancing)
    - 100˚-120˚ (Maximum flexion)

* Joint balancing not required for RESTORIS MCK PFJ procedure because the tibia is not registered.

Intra-Operative Joint Balancing (Pose Capture)

- Obtain pose captures for joint balancing at approximately
    - 5° - 10° knee flexion (Extension gap balancing)



Flexion 5.0°

Varus 2.0°

Internal Rotation 5.0°

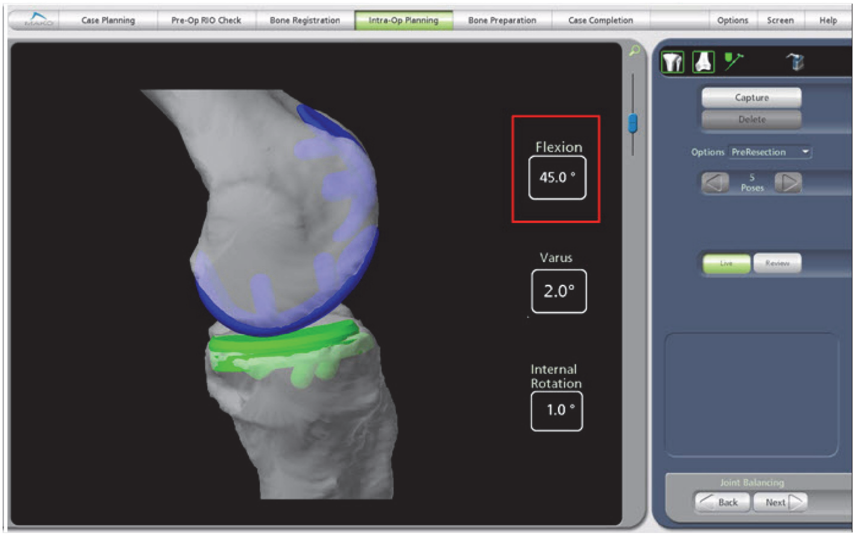
Options PreResection

5 Poses

Case Planning
Pre-Op RIO Check
Bone Registration
Intra-Op Planning
Bone Preparation
Case Completion
Options
Screen
Help
Capture
Delete
Live
Review
Joint Balancing
Back
Next

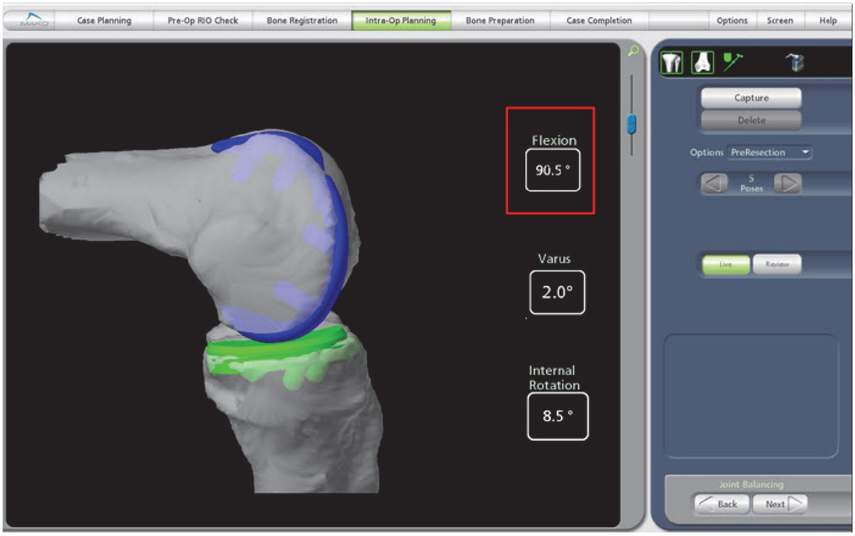
Intra-Operative Joint Balancing (Pose Capture)

- Obtain pose captures for joint balancing at approximately
  - 45° knee flexion (Mid-flexion gap balancing)


Flexion 45.0 °
Varus 2.0°
Internal Rotation 1.0 °
Options PreResection
MAKO
Case Planning
Pre-Op RIO Check
Bone Registration
Intra-Op Planning
Bone Preparation
Case Completion
Options
Screen
Help
Capture
Delete
5 Poses
Live
Review
Joint Balancing
Back
Next

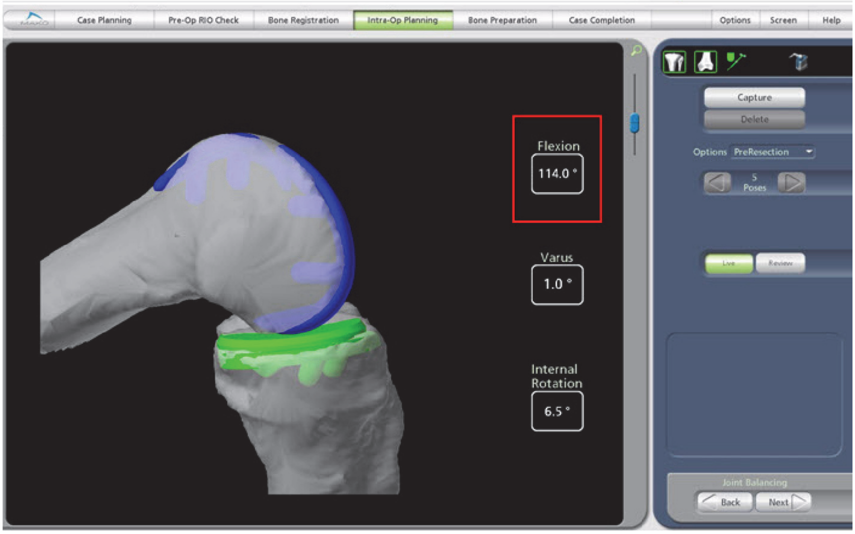
Intra-Operative Joint Balancing (Pose Capture)

- Obtain pose captures for joint balancing at approximately
  - 90° knee flexion (Flexion gap balancing)


Flexion 90.5 °
Varus 2.0°
Internal Rotation 8.5 °
Options PreResection
MAKO
Case Planning
Pre-Op RIO Check
Bone Registration
Intra-Op Planning
Bone Preparation
Case Completion
Options
Screen
Help
Capture
Delete
5 Poses
Live
Review
Joint Balancing
Back
Next

Intra-Operative Joint Balancing (Pose Capture)

- Obtain pose captures for joint balancing at approximately
  - 100° - 120° (Maximum flexion)



Flexion 114.0 °

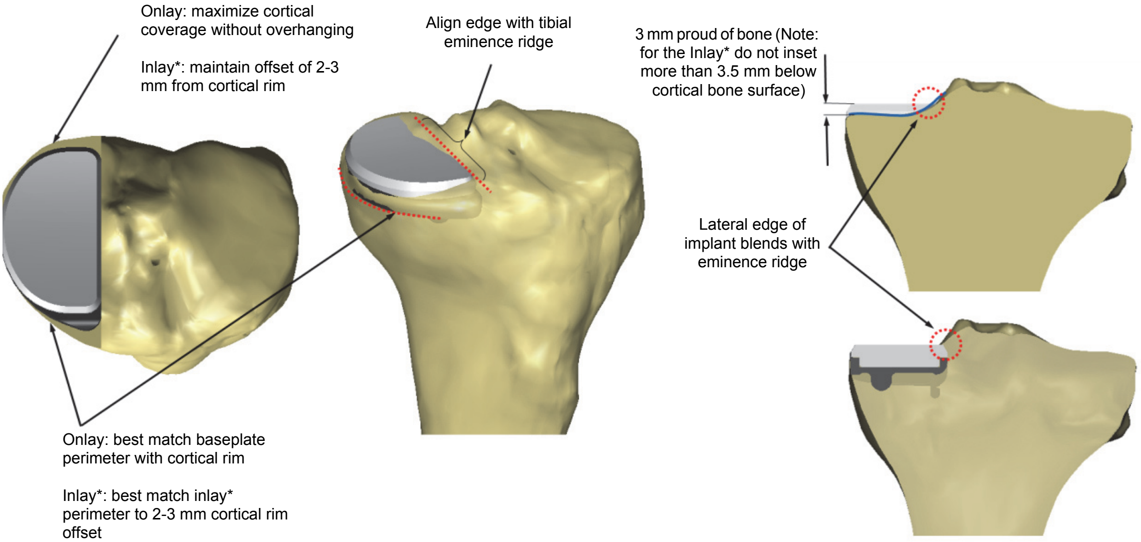
Varus 1.0 °

Internal Rotation 6.5 °

Options PreResection

Case Planning
Pre-Op RIO Check
Bone Registration
Intra-Op Planning
Bone Preparation
Case Completion
Options
Screen
Help
Capture
Delete
5 Poses
Live
Review
Joint Balancing
Back
Next

RESTORIS MCK Tibial Component Intra-Operative Planning: Summary



Onlay: maximize cortical coverage without overhanging

Inlay*: maintain offset of 2-3 mm from cortical rim

Align edge with tibial eminence ridge

3 mm proud of bone (Note: for the Inlay* do not inset more than 3.5 mm below cortical bone surface)

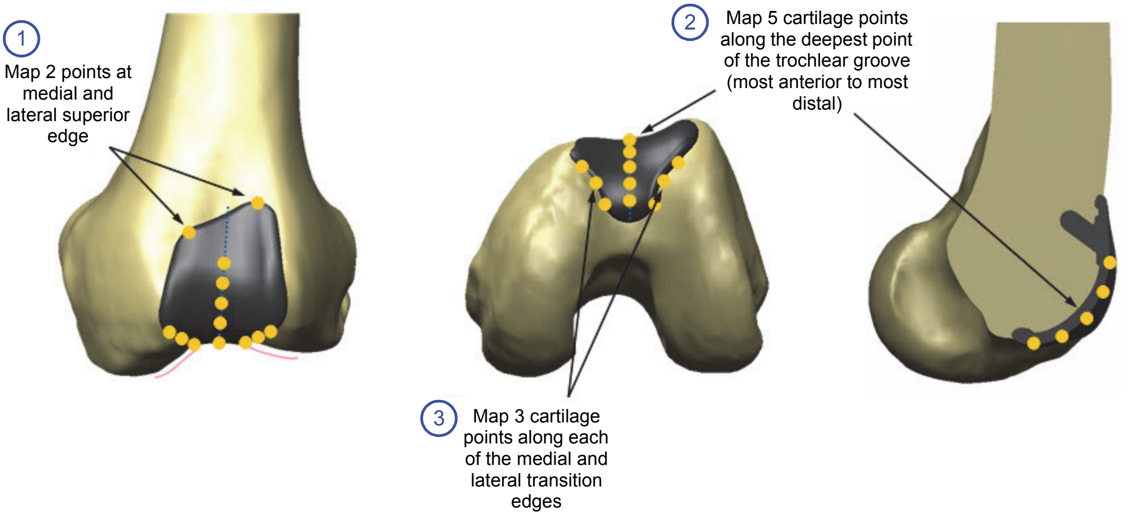
Lateral edge of implant blends with eminence ridge

Onlay: best match baseplate perimeter with cortical rim

Inlay*: best match inlay* perimeter to 2-3 mm cortical rim offset

Set implant in Primary view and scroll through the slices or use the Verify 1 and Verify 2 preset views to verify planning criteria.

Patellofemoral (Trochlear) Intra-Operative Cartilage Mapping



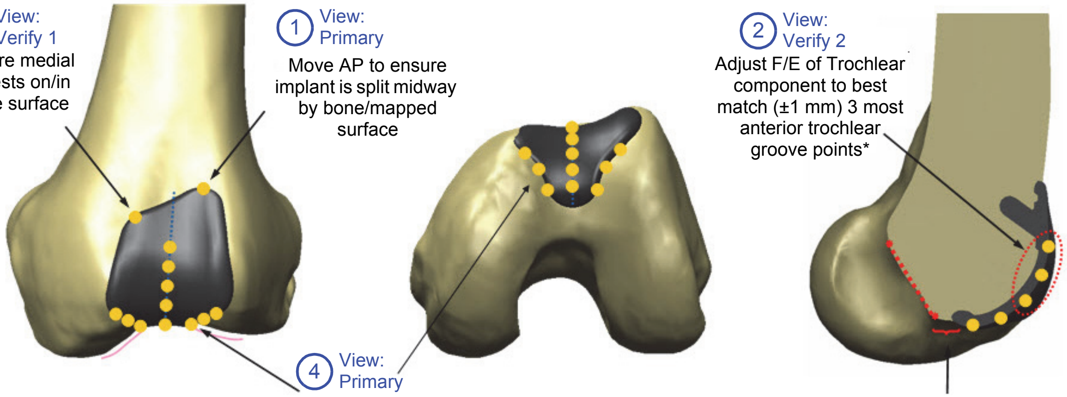
① Map 2 points at medial and lateral superior edge

② Map 5 cartilage points along the deepest point of the trochlear groove (most anterior to most distal)

③ Map 3 cartilage points along each of the medial and lateral transition edges

RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.

Patellofemoral (Trochlear) Intra-Operative Planning Summary



⑤ View: Verify 1

Ensure medial tip rests on/in bone surface

① View: Primary

Move AP to ensure implant is split midway by bone/mapped surface

② View: Verify 2

Adjust F/E of Trochlear component to best match (±1 mm) 3 most anterior trochlear groove points*

④ View: Primary

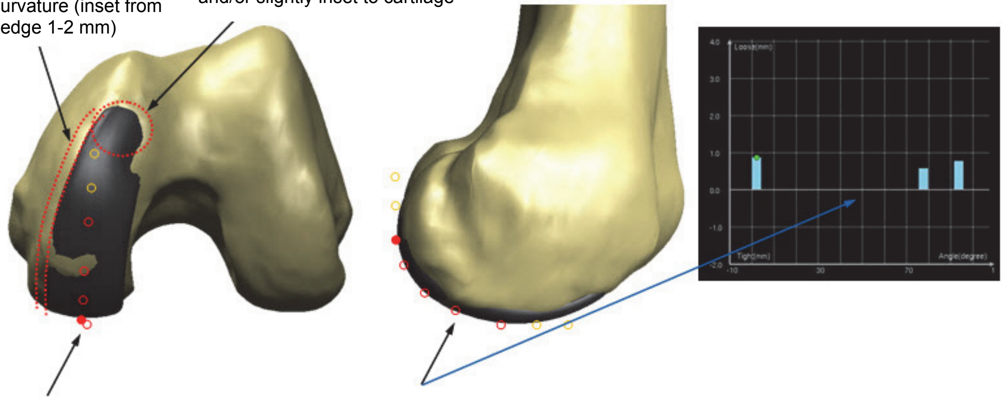
Move Trochlear V/V and S/I to best match (±1 mm) lateral cartilage transition region

*Note: if the mapped points lie on arthritic bone and not cartilage, adjust F/E to be ~2 mm proud of bone surface

Ensure distal tip is anterior to Blumensaat's line

③ View: Verify 2

RESTORIS MCK Femoral Component Intra-Operative Planning: Summary



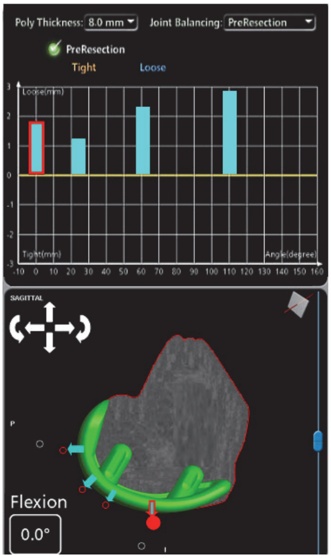
Best match Femoral medial edge to condylar curvature (inset from medial edge 1-2 mm)

Set Femoral anterior tip just proud of bone, below PF wing, and/or slightly inset to cartilage

Best match Femoral High Point Groove to Tibial trace points from Joint Balancing (Pose Capture)

Adjust Femoral to obtain desired joint balancing gap (0-1.5 mm looseness)

Intra-Operative Planning

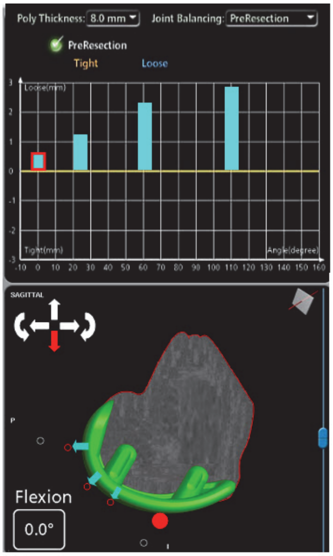

Poly Thickness: 8.0 mm

Joint Balancing: PreResection

Flexion 0.0°
PreResection
Tight
Loose
Loose(mm)
Tight(mm)
Angle(degree)
3
2
1
0
-1
-2
-3
-10 0 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150 160
SAGITTAL
P

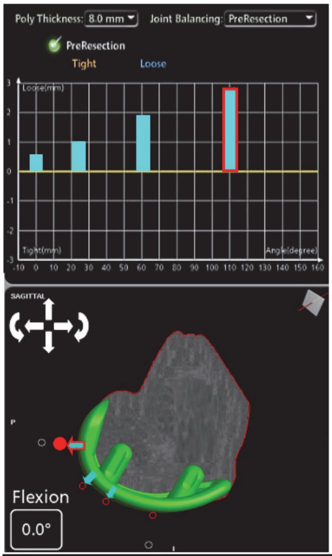
Extension Gap

Adjust femoral SI to set desired extension gap


Poly Thickness: 8.0 mm

Joint Balancing: PreResection

Flexion 0.0°
PreResection
Tight
Loose
Loose(mm)
Tight(mm)
Angle(degree)
3
2
1
0
-1
-2
-3
-10 0 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150 160
SAGITTAL
P

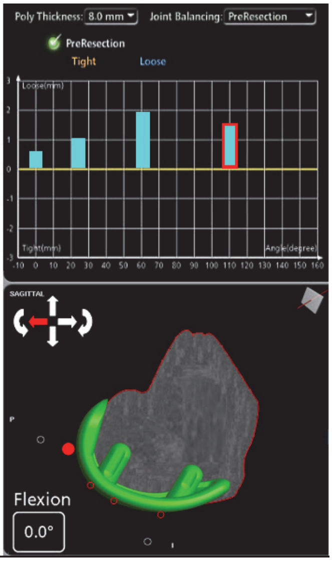

Poly Thickness: 8.0 mm

Joint Balancing: PreResection

Flexion 0.0°
PreResection
Tight
Loose
Loose(mm)
Tight(mm)
Angle(degree)
3
2
1
0
-1
-2
-3
-10 0 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150 160
SAGITTAL
P

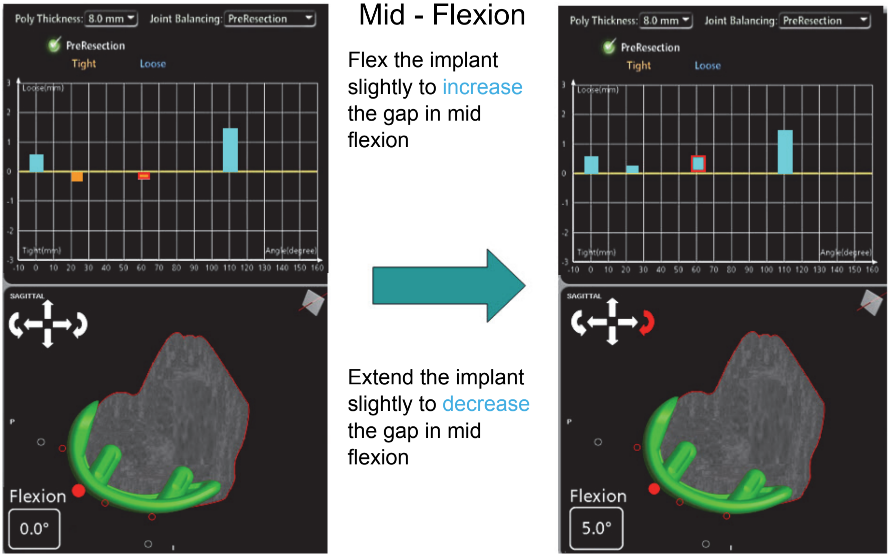
Flexion Gap

Adjust femoral AP to set desired flexion gap


Poly Thickness: 8.0 mm

Joint Balancing: PreResection

Flexion 0.0°
PreResection
Tight
Loose
Loose(mm)
Tight(mm)
Angle(degree)
3
2
1
0
-1
-2
-3
-10 0 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150 160
SAGITTAL
P



Poly Thickness: 8.0 mm
Joint Balancing: PreResection

Mid - Flexion

Flex the implant slightly to increase the gap in mid flexion

Extend the implant slightly to decrease the gap in mid flexion

Quick Fit

Overview

Quick Fit optimizes the placement of the Femoral Condyle component in the sagittal plane (anterior-posterior translation, superior-inferior translation, and optionally flexion-extension rotation) using the inputs from the captured poses from Joint Balancing and the desired gap values entered in Gap Settings or Surgeon Preferences.

Quick Fit is only available when the Femoral Condyle plan is active.

Upon clicking Quick Fit, the Femoral Condyle placement and graph are automatically updated.

Desired Gap Settings

Desired gap values for extension, mid-flexion, and flexion can be set in Gap Settings or Surgeon Preferences. The gap values for each flexion range can vary from -5 mm to +5 mm in 0.5 mm increments. Quick Fit will attempt to achieve all desired gap setting values within their tolerance settings. The tolerance settings for extension, mid-flexion, and flexion are ±0.25 mm, ±1 mm, and ±0.25 mm, respectively. For example, if the desired extension gap is set to 1 mm, Quick Fit may provide an output where the extension gap is 0.75-1.25 mm.

Since extension and flexion gaps are of primary concern to surgeons, these tolerances were set narrower than the mid-flexion tolerance.

If Quick Fit cannot find a solution that meets all the desired gap values set by the user, a warning will be displayed indicating that the gap value for the indicated pose is outside the desired gap range.

Captured Pose Ranges

The extension and flexion pose target angles can be set to a value within 5-25° and 80-150° of flexion, respectively. The extension and flexion pose angle ranges are defined as ±5° of the target value, so the possible extension range is 0-30° flexion and the possible flexion range is 75-155° flexion. If multiple poses are taken within the defined range, only the pose closest to the target angle will be included in Quick Fit. The mid-flexion pose range can be within 31-74°of flexion. All poses taken within the mid-flexion range will be included in Quick Fit.

If no poses are taken within the defined ranges, clicking Quick Fit will result in a warning instructing the user to take a pose within the indicated range.

Only poses captured within the specified pose ranges are used in the Quick Fit calculations.

Anterior Tip Fit

Literature suggests that femur cartilage thickness near the Femoral Condyle anterior tip is approximately 2 mm, but each patient's cartilage thickness is unique and could vary from 1-3 mm thick. It is recommended that the surgeon maps cartilage near the anterior tip to ensure that the Femoral Condyle component does not impinge with the patella during knee flexion. The distance from the anterior tip to the bone is always displayed in the information box even if cartilage is not mapped. Quick Fit will attempt to place the anterior tip of the Femoral Condyle component between 1 mm and 3 mm proud of the bone. If the maximum tip distance is greater than 2 mm, the information box will display a yellow message advising the surgeon to map cartilage along the anterior tip. If proud of the cartilage, the surgeon should make manual adjustments until the anterior tip is flush with or recessed below cartilage. Peer-reviewed literature suggests that recessing the anterior tip does not affect UKA outcomes [1,2]. However, additional warnings will be displayed if the tip is excessively recessed (approximately 5 mm deep) or excessively proud (>3 mm proud).

The surgeon then must exercise good medical judgment if changes need to be made to the implant plan.

References:

1. *Simultaneous In-vitro Measurement of Patellofemoral Kinematics and Forces Following Oxford Medial Unicompartmental Knee Arthroplasty. A Price, PT Oppold, DW Murray, AB Zavatsky. Journal of Bone and Joint Surgery [Br] 2006; 88-B: 1591-1595. Price et al.In vitro measurement of PF kinematics and forces following Oxford medial UKA.JBJS-Br. 2006.*
2. *The influence of the presence and severity of pre-existing patellofemoral degenerative changes on the outcome of the Oxford medial unicompartmental knee replacement. Beard DJ, Pandit H, Gill HS, Hollinghurst D, Dodd CA, Murray DW. Journal of Bone and Joint Surgery [BR] 2007; Dec; 89(12):1597-601.*

Since each patient has a unique cartilage thickness near the anterior tip of the Femoral Condyle component, it is recommended that the surgeon maps the cartilage surface near the anterior tip to avoid patella impingement. If the anterior tip is proud of the cartilage after Quick Fit, the surgeon can manually make adjustments to the implant plan to achieve the desired placement.

This feature does not replace the need for cartilage mapping.

Mid-Flexion and Femoral Condyle Rotation

When Mid-Flexion is checked in the Gap Settings, the Femoral Condyle component flexion rotation angle will be adjusted to best match the desired mid-flexion gap setting, while staying within the recommended positioning limits (5° extension to 5° flexion rotation). If the user prefers a different flexion rotation angle or one outside the recommended positioning limits, then Mid-Flexion can be unchecked and Quick Fit will only translate the Femoral Condyle component to meet the desired extension and flexion gap settings.

Quick Fit provides a quick and easy suggested position of the Femoral Condyle component based on the inputs of the surgeon (poses and gap settings for a given Tibial component plan). The surgeon should fully consider all gap values for all poses even if certain poses are not used by Quick Fit. For example, if the target flexion pose angle is 90° and poses were taken at 93° and 115° flexion, only the pose at 93° will be used by Quick Fit, but the gap value at 115° should be considered before accepting the final plan. Final acceptance of the implant plan must still be made by the surgeon.

⚠ *Quick Fit does not adjust Femoral Condyle medial-lateral translation, varus-valgus rotation, and internal-external rotation. Therefore, the surgeon still must manually adjust these settings for proper placement. Quick Fit does not adjust Tibial component placement.*

📌 *If the Tibial or Femoral Condyle component position or size is changed after Quick Fit has been performed, Quick Fit will need to be executed again.*

📌 *As with any optimization, the output is only as good as the input. If the ligaments are not properly tensioned and/or the limb is not properly aligned during Joint Balancing pose captures, Quick Fit cannot be expected to provide a proper clinical outcome.*

Kinematic Analysis

Overview

During either component trial evaluation or final implant evaluation, the Kinematic Analysis page provides the surgeon the ability to quantify post-resection limb alignment in extension, joint gaps, and kinematic range of motion. This page also enables the user to compare post-resection limb alignment and joint gaps to pre-resection values. This page is available, but not required for completing a MAKOplasty.

Capture Contact

To enable the features in Kinematic Analysis, contact poses must first be taken. Capture contact poses from full extension to full flexion to record full range of motion. Ensure that the trials/implants are in continuous contact with each other throughout range of motion. When capturing contact poses, apply neutral internal/external rotation torque on the tibia and let the soft tissue guide its natural motion.

📌 *Contact poses are necessary to zero out the errors due to bone registration, over/under resection of bone, and due to introduction of cement after implantation.*

⚠ *The trial or implant insert thickness used during Capture Contact must be the same as the Poly thickness selected in the drop down menu. If they are not, errors in the gap values may result.*

⚠ *The tibial and femoral arrays should not be moved after resection in order for the Kinematic Analysis page to work for both trialing and implantation options.*

Gap Graph

Selecting the graph icon displays the Gap Graph at the top of the page. To view the pre-resection gap values, toggle on Pre-Resection. The Gap Graph can display gap values for all poses taken during pre-resection and post-resection for comparison.

Live Kinematic Values

After contact poses are collected, live kinematic values are displayed in both sagittal and coronal planes.

Flexion Angle. The live flexion angle of the knee is displayed in the sagittal window. When Pre-Resection is toggled on, the sagittal kinematic window will display blue dots on the flexion dial, indicating the flexion angles where pre-resection poses were taken. When the knee is within ±5° flexion of the pre-resection pose, pre-resection values will be displayed in the coronal window. Outside the ±5° flexion range of pre-resection, the value boxes will display N/A.

Tibiofemoral Varus/Valgus. The coronal window displays three values of tibiofemoral varus/valgus. The ‘Contact’ values are the angles recorded during ‘Capture Contact’. The ‘Varus’ (or Valgus) value is the live varus/valgus angle of the knee in the current pose. When Pre-Resection is toggled on and the knee is within ±5° flexion of the pre-resection pose, the ‘Pre-resection’ value recorded during Joint Balancing is displayed. The live varus/valgus angle should only be compared to the Pre-resection angle when the same varus/valgus moment is applied to the knee as during pre-resection Joint Balancing.

Internal/External Rotation. The coronal kinematic window displays the relative difference (delta) of the current internal/external rotation (axial rotation) to that taken during the contact pose.When Pre-Resection is toggled on and the knee is within ±5° flexion of the pre-resection pose, a blue dot will appear on the delta axial rotation dial indicating the axial rotation difference between the contact pose and pre-resection pose. For best comparison to pre-resection values, the blue dot should be within the delta window.

Capture Gap

The ‘Gap’ value is the joint space between the Femoral and Tibial components. This value should read zero when no moment is applied to the leg. To view the joint gap value at any flexion angle, apply the same varus/valgus moment that was applied during Joint Balancing. Visually confirm that the actual gap seen matches that displayed in the gap value box.When Pre-Resection is toggled on and the knee is within ±5° flexion of the pre-resection pose, the ‘Pre-resection’ gap value recorded during Joint Balancing is displayed.

Click ‘Capture Gap’ to record the gap for a given flexion angle in the bar graph. To compare post-resection gaps to pre-resection gaps, it is best to obtain joint gaps within ±5° flexion of the pre-resection poses. However, there is no limitation on how many post-resection gaps can be obtained, but flexion angles are limited to those collected during contact poses.

For most accurate results, capture the gap when the knee is within ±5° of axial rotation of the contact pose. Adjust the axial rotation of the knee until the rotation bar is within the ±5° delta window. The delta window will turn to a different color when within the proper range.

If the gap values are larger than desired, changing the Poly thickness in the drop down menu after ‘Capture Contact’ can be used to predict the effect of a thicker trial/implant.

📌 *The gap value should not be negative unless axial rotation was excessively outside that taken during pre-resection or if the trials/implants were not touching during contact pose captures.*

📌 *The post-resection gap may be less or greater than the pre-resection value if the varus/valgus moment is not the same as in pre-resection, if there are joint changes due to bone resection such as release of capsular adhesions and/or additional osteophyte removal, or if axial rotation is outside the axial rotation delta window.*

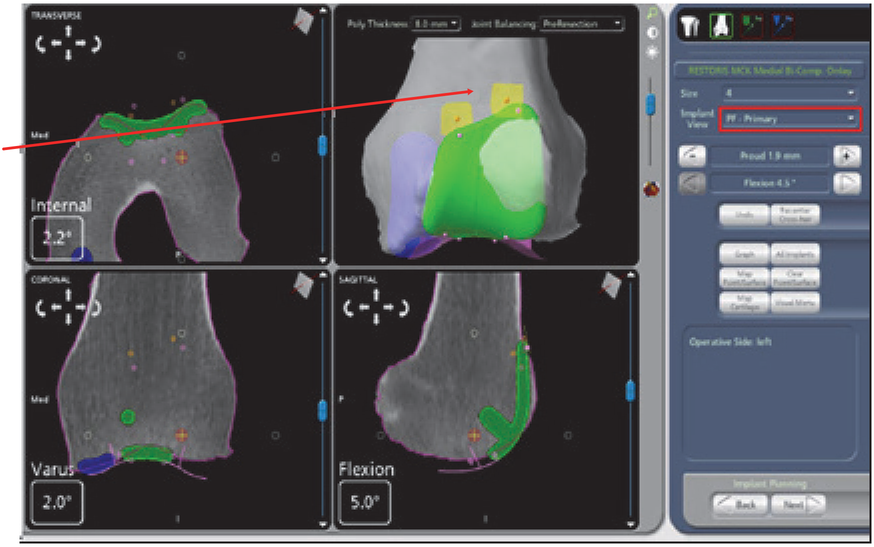
⚠ *It is recommended that the trial or implant insert thickness used during joint gap evaluation be the same as the poly thickness selected in the drop down menu. If they are not, errors in the values may result.*

⚠ *If the trial or implant insert thickness is changed, it is recommended that you delete the captured gap poses and recapture new contact and gap poses.*

Patellofemoral Component

Intra-Operative Patellofemoral Planning

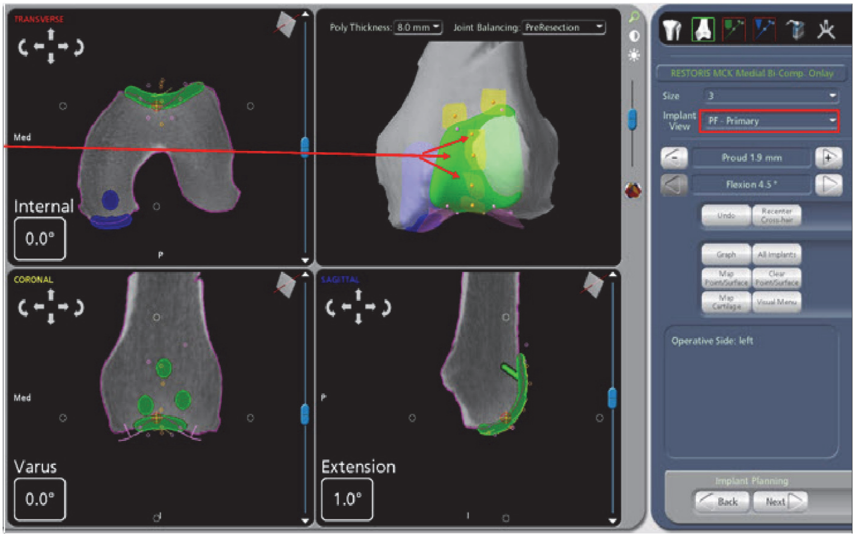
- Select 'PF-Primary'
- Map Cartilage / Bone
  - Map 2 bone points on the proximal edge near the medial and lateral violet tip points
  - Edge points will ensure that the implant is placed midway through bone surface


TRANSVERSE
Med
Internal
2.2°
CORONAL
Med
Varus
2.0°
SAGITTAL
P
Flexion
5.0°
Undo
Recenter Cross-hair
Graph
All implants
Map Point/Surface
Clear Point/Surface
Map Cartilage
Visual Menu
Implant Planning
Back
Next

Poly Thickness: 8.0 mm
Joint Balancing: PreResection
RESTORIS MCK Medial Bi-Comp. Onlay
Size: 4
Implant View: PF - Primary
Proud 1.9 mm
Flexion 4.5°
Operative Side: left

Intra-Operative Patellofemoral Planning

- Map Cartilage / Bone
- Map 5 cartilage points along the deepest point of the trochlear groove (most anterior to most distal)


TRANSVERSE
Med
Internal
0.0°
P
CORONAL
Med
Varus
0.0°
SAGITTAL
P
Extension
1.0°
Undo
Recenter Cross-hair
Graph
All implants
Map Point/Surface
Clear Point/Surface
Map Cartilage
Visual Menu
Implant Planning
Back
Next

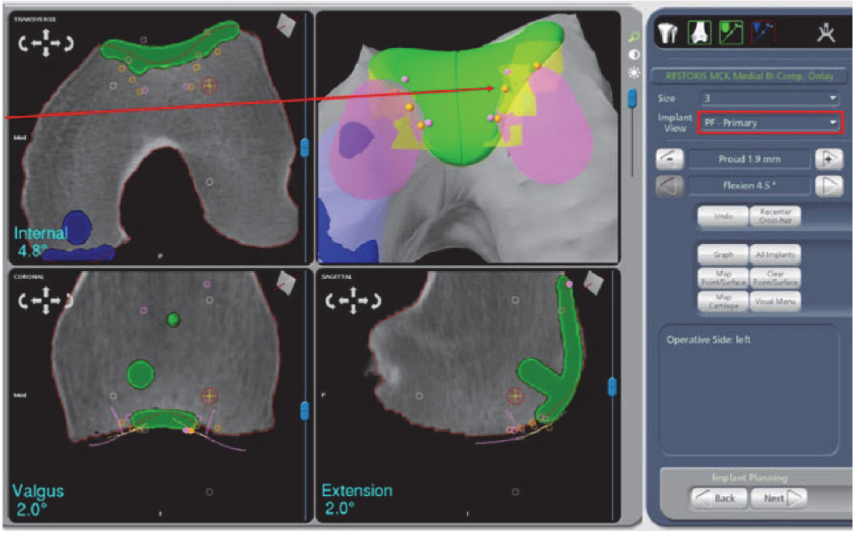
Poly Thickness: 8.0 mm
Joint Balancing: PreResection
RESTORIS MCK Medial Bi-Comp. Onlay
Size: 3
Implant View: PF - Primary
Proud 1.9 mm
Flexion 4.5°
Operative Side: left

Intra-Operative Patellofemoral Planning

- Map Cartilage / Bone
  - Map a minimum of 3 cartilage points on each of the lateral and medial PF patellar transition zone edges

  Selecting edge points next to the 2 violet points and 1 edge point in between will provide ideal spacing

  NOTE: These 13 are the minimum recommended points to be mapped, more points can be collected as needed to ensure a successful implant plan


TRANSVERSE
Med
P
Internal
4.8°
CORONAL
Med
Valgus
2.0°
SAGITTAL
P
Extension
2.0°
Undo
Recenter Cross-hair
Graph
All Implants
Map Point/Surface
Clear Point/Surface
Map Cartilage
Visual Menu
Implant Planning
Back
Next

RESTORIS MCK Medial Bi Comp. Onlay

Size: 3

Implant View: PF - Primary

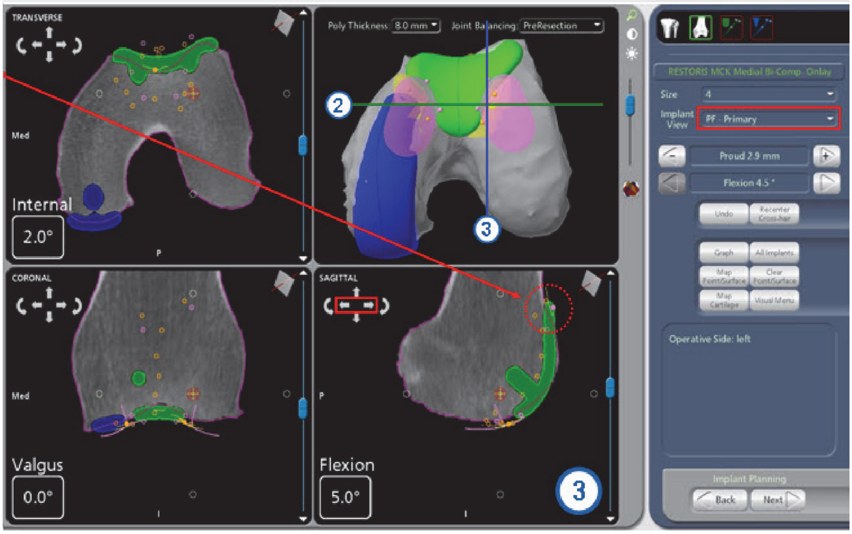
Proud 1.9 mm

Flexion 4.5 °

Operative Side: left

Intra-Operative Patellofemoral Planning

③ Adjust AP so that PF is split midway by mapped surface


TRANSVERSE
Med
P
Internal
2.0°
2
3
CORONAL
Med
Valgus
0.0°
SAGITTAL
P
Flexion
5.0°
3
Undo
Recenter Cross-hair
Graph
All Implants
Map Point/Surface
Clear Point/Surface
Map Cartilage
Visual Menu
Implant Planning
Back
Next

Poly Thickness: 8.0 mm

Joint Balancing: PreResection

RESTORIS MCK Medial Bi Comp. Onlay

Size: 4

Implant View: PF - Primary

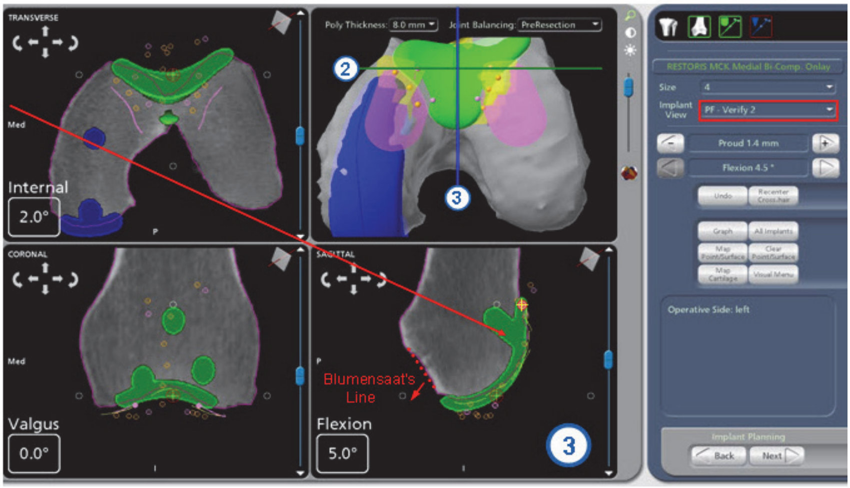
Proud 2.9 mm

Flexion 4.5 °

Operative Side: left

Intra-Operative Patellofemoral Planning

- Select ‘PF-Verify 2’
- ③ Set the crosshair at the proximal implant in the Sagittal view
- Adjust F/E of Trochlear component to best match (± 1 mm) the 3 most anterior trochlear groove points
  - NOTE: if the mapped points lie on arthritic bone and not cartilage, adjust F/E to be ~2 mm proud of bone surface
- **Verify ACL notch**
  - PF distal tip should be anterior to Blumensaat’s line

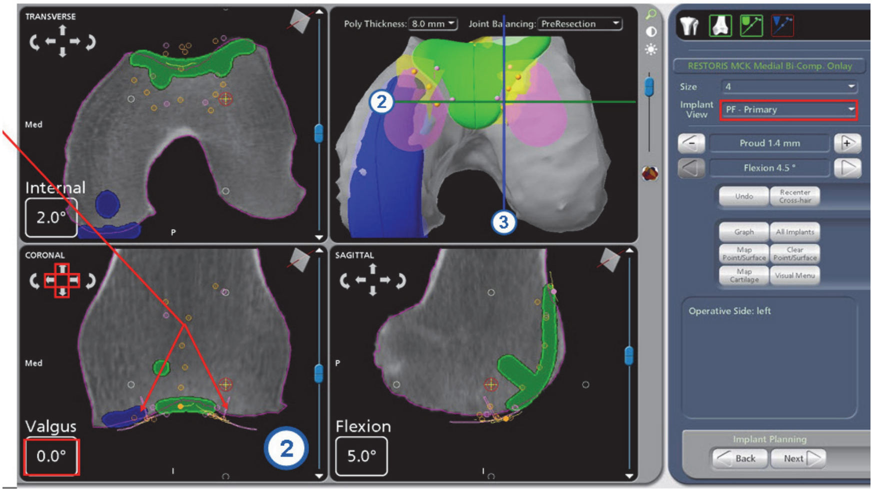


Poly Thickness: 8.0 mm
Joint Balancing: PreResection
Size: 4
Implant View: PF - Verify 2
Proud 1.4 mm
Flexion 4.5°
Operative Side: left

TRANSVERSE
Med
Internal
2.0°
P
CORONAL
Valgus
0.0°
SAGITTAL
Blumensaat's Line
Flexion
5.0°
2
3
RESTORIS MCK Medial Bi-Comp. Onlay
Undo
Recenter Cross-hair
Graph
All Implants
Map Point/Surface
Clear Point/Surface
Map Cartilage
Visual Menu
Implant Planning
Back
Next

Intra-Operative Patellofemoral Planning

- Select ‘PF-Primary’
- ③ Adjust V/V and SI to best match patellar transition zones to mapped lateral cartilage
  - If lateral cartilage is thicker than medial cartilage, match lateral cartilage
  - If medial cartilage is thicker than lateral cartilage, match PF to be halfway between medial and lateral cartilage

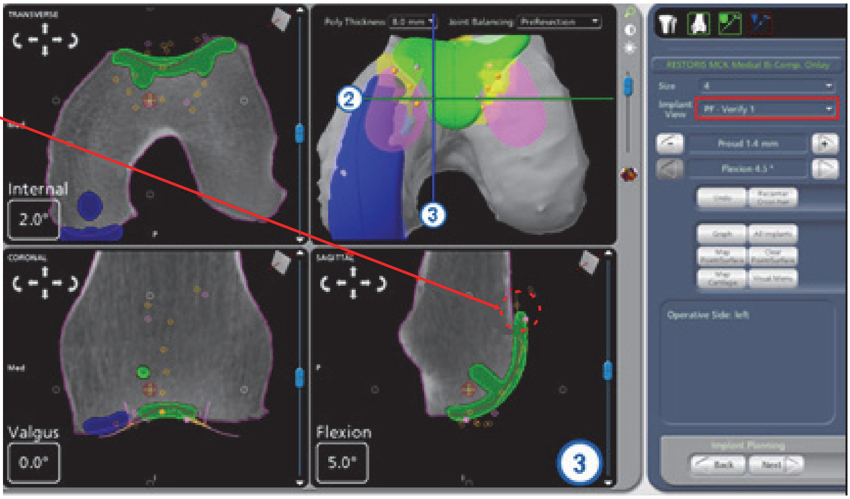


Poly Thickness: 8.0 mm
Joint Balancing: PreResection
Size: 4
Implant View: PF - Primary
Proud 1.4 mm
Flexion 4.5°
Operative Side: left

TRANSVERSE
Med
Internal
2.0°
P
CORONAL
Valgus
0.0°
SAGITTAL
Flexion
5.0°
2
3
RESTORIS MCK Medial Bi-Comp. Onlay
Undo
Recenter Cross-hair
Graph
All Implants
Map Point/Surface
Clear Point/Surface
Map Cartilage
Visual Menu
Implant Planning
Back
Next

Intra-Operative Patellofemoral Planning

- Select ‘PF-Verify 1’
- ③ Verify that the PF rests on or in mapped surface
  - If the mapped surface is inside the PF, no action is required
  - If PF does not contact mapped surface, translate posterior until PF contacts mapped surface
  - Note: Moving the PF in this view will change the fit in the previous step



TRANSVERSE
Internal
2.0°
Poly Thickness
Joint Balancing
②
③
CORONAL
Valgus
0.0°
SAGITTAL
Flexion
5.0°
③
RESTORIS MCK Medial Bi-Comp. Onlay
Proud 1.4 mm
Flexion 4.5 °
Graph
All implants
Implant Planning
Back
Next

Size: 4

Implant View: PF - Verify 1

Operative Side: left

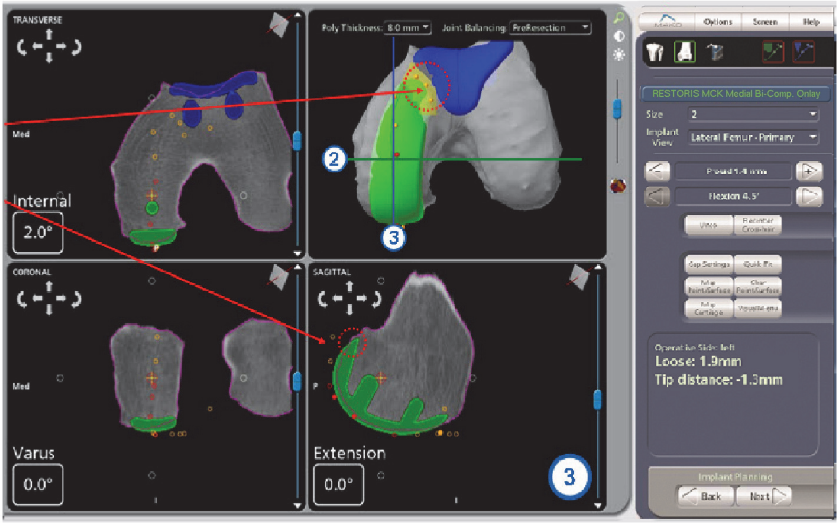
Femoral Component

Intra-Operative Femoral Planning – Verify Size

- Select ‘Medial Femur – Primary’

③ Verify intercomponent gap ≥3 mm and Femoral has full posterior condyle coverage

- Map cartilage points in transition region to ensure smooth patella handoff

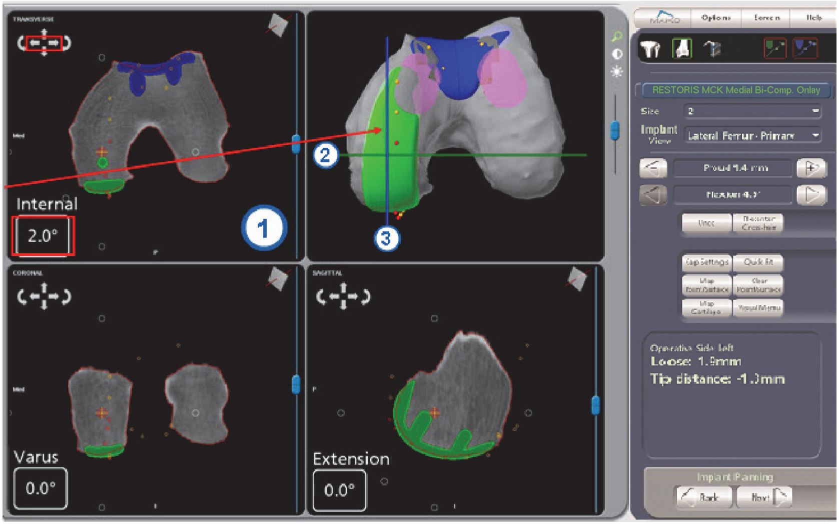

TRANSVERSE
Med
CORONAL
Med
SAGITTAL
P
2
3
3
Options
Screen
Help
RESTORIS MCK Medial Bi-Comp. Onlay
Gap Settings
Quick Fit
Map Point/Surface
Clear Point/Surface
Map Cartilage
Visual Menu
Implant Planning
Back
Next

Poly Thickness: 8.0 mm
Joint Balancing: PreResection
Internal 2.0°
Varus 0.0°
Extension 0.0°
Size 2
Implant View Lateral Femur - Primary
Proud 1.4 mm
Flexion 4.5°
Operative Side: left
Loose: 1.9mm
Tip distance: -1.3mm

Intra-Operative Femoral Planning – Fit

① Adjust I/E and/or ML to align Femoral High Point Groove to Tibial tracking points as best as possible
  - This will aid in central Tibial component
  - The Femoral High Point Groove is the probable tibial tracking pathway

Note: For better visualization, set Implant View to ‘Tibia – Primary’ and turn on ‘All Implants’ to cycle through the flexion angles and watch the actual tracking of the femoral component on the tibia component


TRANSVERSE
Med
CORONAL
Med
SAGITTAL
P
1
2
3
Options
Screen
Help
RESTORIS MCK Medial Bi-Comp. Onlay
Gap Settings
Quick Fit
Map Point/Surface
Clear Point/Surface
Map Cartilage
Visual Menu
Implant Planning
Back
Next

Internal 2.0°
Varus 0.0°
Extension 0.0°
Size 2
Implant View Lateral Femur - Primary
Proud 1.4 mm
Operative Side: left
Loose: 1.9mm
Tip distance: -1.3mm

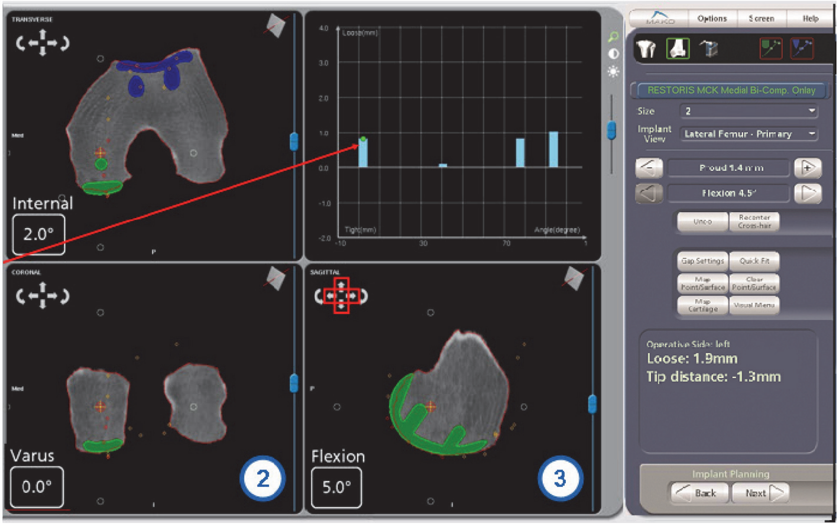
Intra-Operative Femoral Planning – Fit

② Adjust V/V to match PF component or to better match Tibial tracking points, but stay within positioning limits

③ Adjust F/E, AP, and SI to obtain desired joint balancing gap

- Goal: 0-1.5 mm looseness in graph
- If mid-flexion gap is tight, flex Femoral
- If mid-flexion gap is loose, extend Femoral

Note: If Quick Fit is enabled, use Quick Fit at this time.


TRANSVERSE
Med
Internal
2.0°
Loose(mm)
4.0
3.0
2.0
1.0
0.0
-1.0
-2.0
Tight(mm)
Angle(degree)
-10
30
70
CORONAL
Varus
0.0°
2
SAGITTAL
Flexion
5.0°
3
MAKO
Options
Screen
Help
RESTORIS MCK Medial Bi-Comp. Onlay
Size
2
Implant View
Lateral Femur - Primary
Proud 1.4 mm
Flexion 4.5°
Undo
Recenter Cross-hair
Gap Settings
Quick Fit
Map Point/Surface
Clear Point/Surface
Map Cartilage
Visual Menu
Implant Planning
Back
Next

Operative Side: left
Loose: 1.9mm
Tip distance: -1.3mm

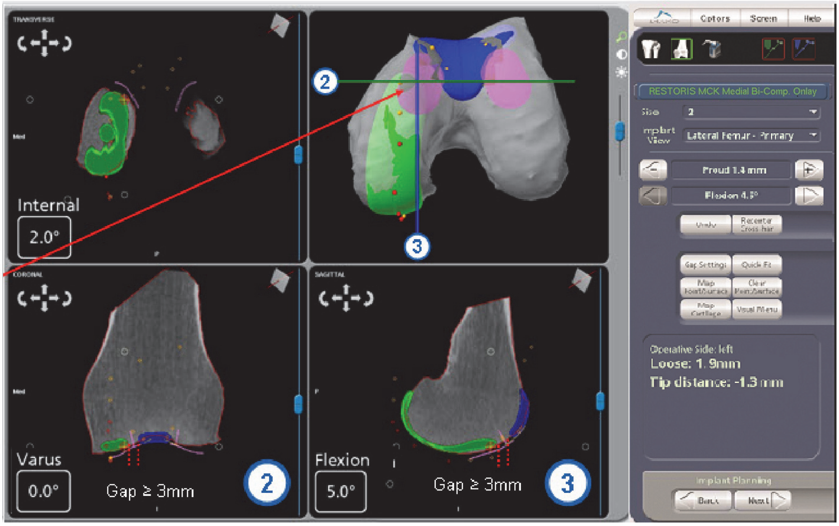
Intra-Operative Femoral Planning – Verify Fit

- Select 'Medial Femur – Verify 1'

② Verify intercomponent gap is ≥3 mm and the Femoral does not protrude through patellar transition zone

③ Verify intercomponent gap is ≥3 mm and the Femoral does not protrude through patellar transition zone

- Anterior tip of Femoral component should be slightly proud of bone
- For a UKA, the Femoral component should not be proud of the mapped cartilage surface


TRANSVERSE
Med
Internal
2.0°
2
3
CORONAL
Varus
0.0°
Gap ≥ 3mm
2
SAGITTAL
Flexion
5.0°
Gap ≥ 3mm
3
Options
Screen
Help
RESTORIS MCK Medial Bi-Comp. Onlay
Size
2
Implant View
Lateral Femur - Primary
Proud 1.4 mm
Flexion 4.5°
Undo
Recenter Cross-hair
Gap Settings
Quick Fit
Map Point/Surface
Clear Point/Surface
Map Cartilage
Visual Menu
Implant Planning
Back
Next

Operative Side: left
Loose: 1.9mm
Tip distance: -1.3 mm

APPENDIX C

RESTORIS MCK lateral Unicondylar Implant Planning Pre-Operative Sequence

- This is the recommended procedural sequence
- This sequence was designed to limit the number of times switching between components
- The sequence can be performed in a different order, but additional component adjustment may be necessary

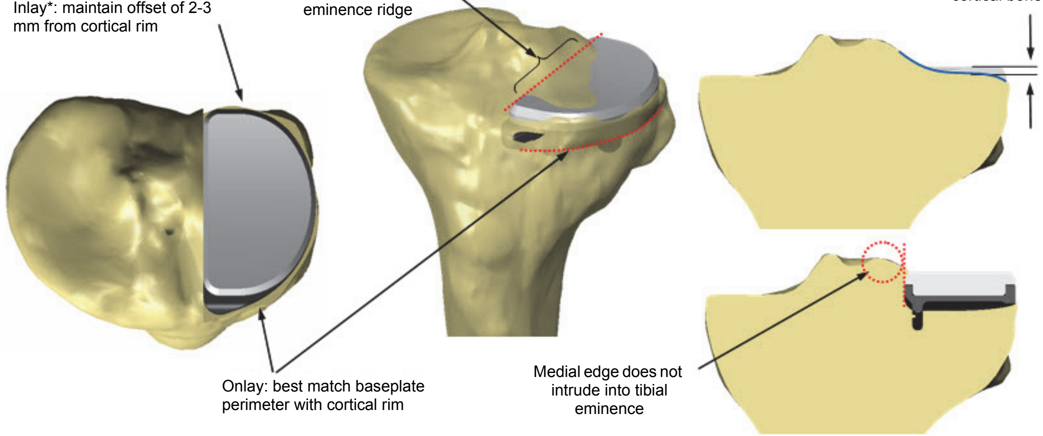
Tibial

- Drag from Default location to approximate location
- Size (repeat above step if size changed)
- Fit (rotate and translate)
- Verify fit

Femoral

- Drag from Default location to approximate location (if necessary)
- Verify size (re-drag if size changed)
- Fit (rotate and translate)
- Verify fit

RESTORIS MCK Tibial Component Pre-Operative Planning: Summary



Onlay: maximize cortical coverage without overhanging

Inlay*: maintain offset of 2-3 mm from cortical rim

Slightly internally rotated with respect to tibial eminence ridge

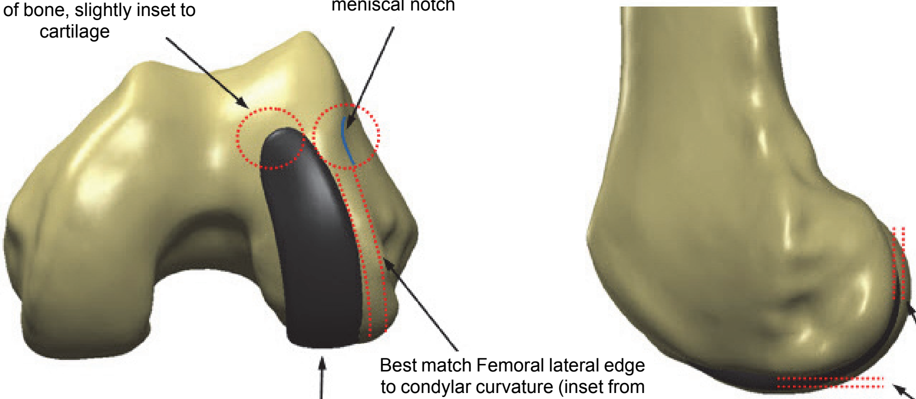
3 mm proud of bone (note: for the Inlay* do not inset more than 3.5 mm below cortical bone surface)

Onlay: best match baseplate perimeter with cortical rim

Inlay*: best match inlay* perimeter to 2-3 mm cortical rim offset

Medial edge does not intrude into tibial eminence

RESTORIS MCK Femoral Component Pre-Operative: Summary



Set Femoral anterior tip just proud of bone, slightly inset to cartilage

Size Femoral by aligning to meniscal notch

Best match Femoral lateral edge to condylar curvature (inset from lateral edge ~1 mm)

Centralize component on condyle

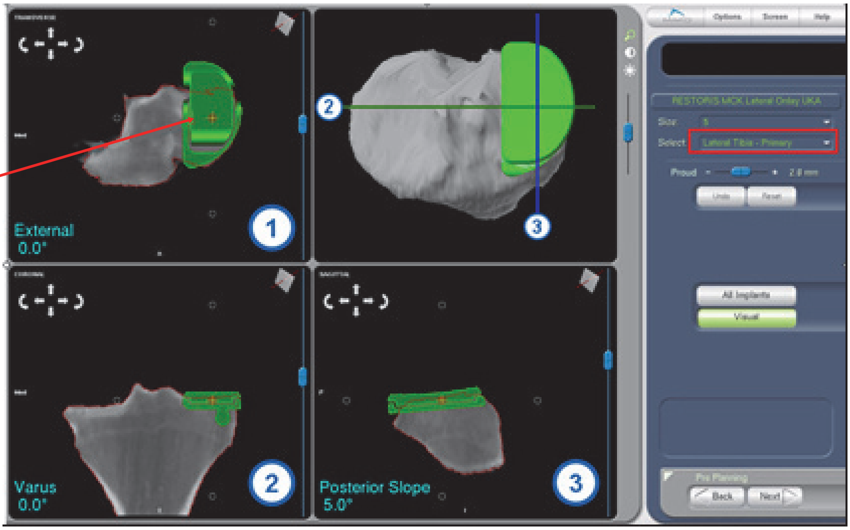
Best match sagittal J-curve, offset from bone ~1 mm

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

Tibial Component: Lateral Unicondylar

Pre-Operative Tibial Planning – Default Position

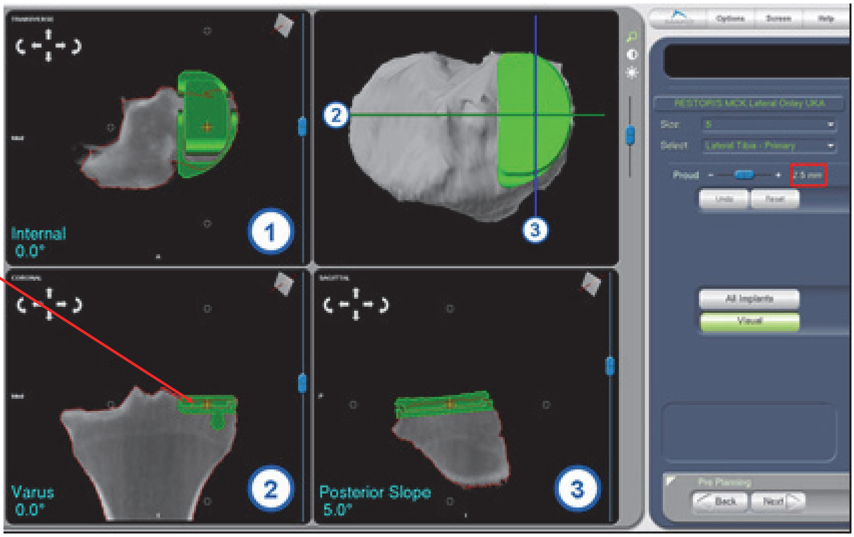
- Component is imported in Default location
- Size 5 is Default size
- Select ‘Lateral Tibia-Primary’
  - Crosshair automatically positioned at implant center:
  - ① 3.5 mm from top
  - ② Center of medial peg
  - ③ ML midplane
  - 3D view set to Transverse (Proximal)


External
0.0°
1
2
3
Varus
0.0°
2
Posterior Slope
5.0°
3
Options
Screen
Help
RESTORIS MCK Lateral Onlay UKA
Size: 5
Select: Lateral Tibia - Primary
Proud
Undo
Reset
All Implants
Visual
Pre Planning
Back
Next

Pre-Operative Tibial Planning – Drag

- ① Drag and drop component into a rough AP and ML position
- ③ Drag component to ~3 mm proud

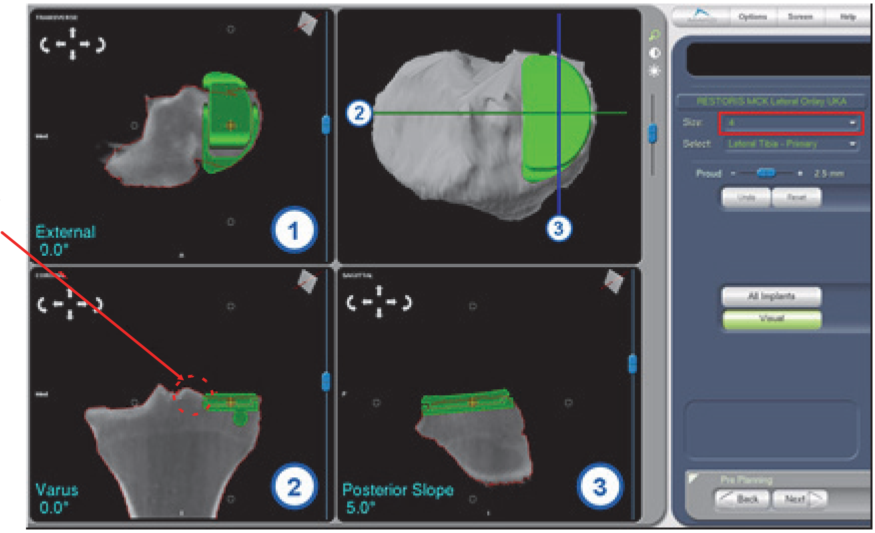
- Onlay visual gap:
  - Gap created to distinguish between Baseplate & Insert
  - Note: gap created by removing material from Insert so Baseplate shown corresponds to actual geometry


Internal
0.0°
1
2
3
Varus
0.0°
2
Posterior Slope
5.0°
3
Options
Screen
Help
RESTORIS MCK Lateral Onlay UKA
Size: 5
Select: Lateral Tibia - Primary
Proud
Undo
Reset
All Implants
Visual
Pre Planning
Back
Next

Pre-Operative Tibial Planning – Size

① ② ③ Determine Tibial Component size:

- Onlay
  - Ideal size is largest component that will not overhang AP, ML, and not intrude into tibial intercondylar eminence
- Inlay*
  - Ideal size is largest component that is 2-3 mm from cortical rim and not intrude into tibial intercondylar eminence



RESTORIS MCK Lateral Onlay UKA

Size: 4

Select: Lateral Tibia - Primary

Proud 2.5 mm

TRANSVERSE
Med
External
0.0°
1
2
3
CORONAL
Med
Varus
0.0°
2
SAGITTAL
Posterior Slope
5.0°
3
Options
Screen
Help
Undo
Reset
All Implants
Visual
Pre Planning
Back
Next

Tibial Planning – Recommended Positioning Limits

Tibial Onlay

① 10° internal ↔ 5° external
AP: on cortical rim

② 0° valgus ↔ 1.5° valgus
ML: on cortical rim

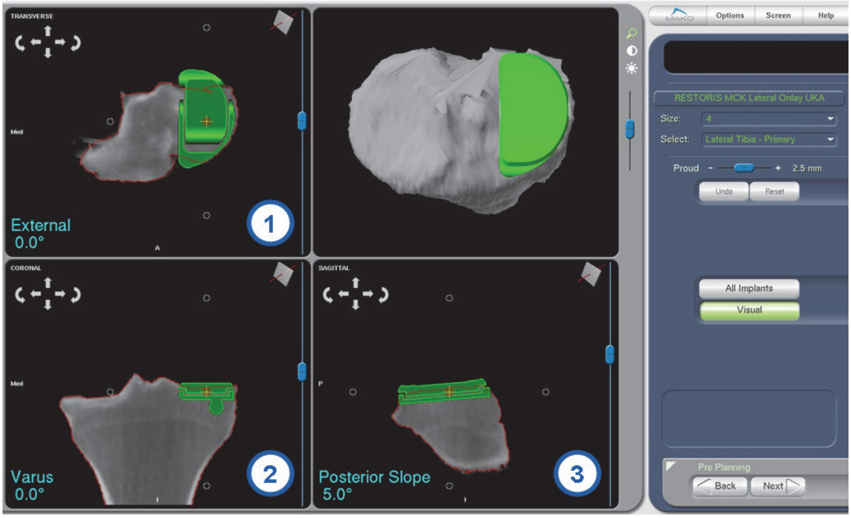
③ 0° slope ↔ 7° slope
SI: 2.5-3.5 mm proud

Tibial Inlay*

① 10° internal ↔ 5° external
AP: 2-3 mm from cortical rim

② 1° valgus ↔ 3° valgus
ML: 2-3 mm from cortical rim

③ 0° slope ↔ 7° slope
SI: 2.5-3.5 mm proud



RESTORIS MCK Lateral Onlay UKA

Size: 4

Select: Lateral Tibia - Primary

Proud 2.5 mm

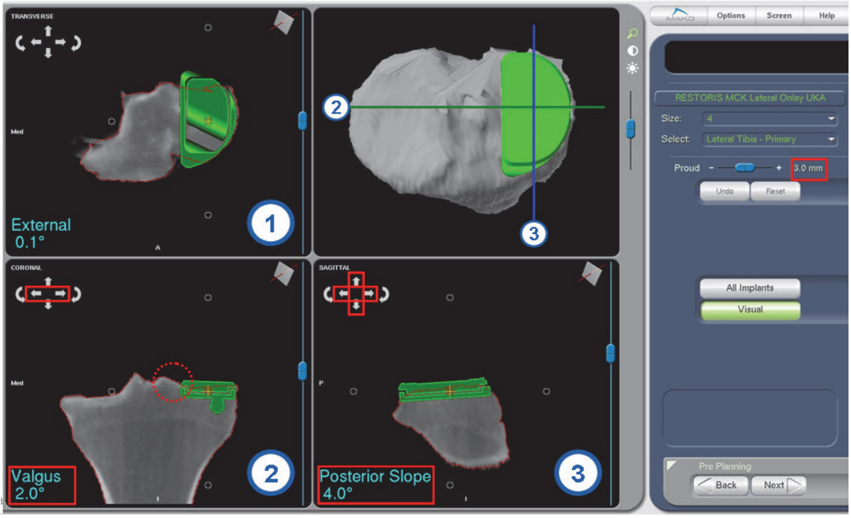
TRANSVERSE
Med
A
External
0.0°
1
CORONAL
Med
Varus
0.0°
2
SAGITTAL
P
Posterior Slope
5.0°
3
MAKO
Options
Screen
Help
Undo
Reset
All Implants
Visual
Pre Planning
Back
Next

RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.

Pre-Operative Tibial Planning – Fit

③ Adjust posterior slope to be slightly less than patient tibial bone slope
  - Removal of meniscus and excessive slope can stress the ACL
- Adjust proudness to 3 mm
- Adjust AP position:
  - Onlay: avoid overhang
  - Inlay*: 2-3 mm inset from cortical rim

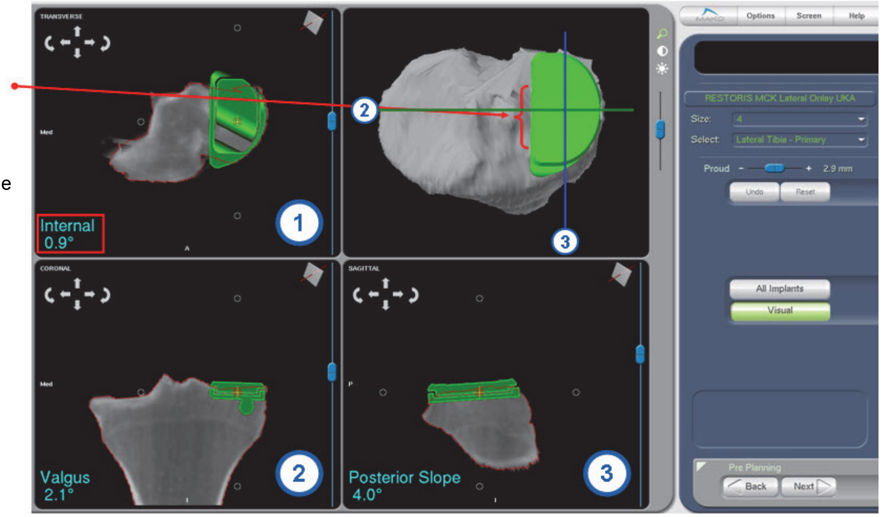
② Adjust V/V:
  - Onlay: stay within positioning limits
  - Inlay*: adjust to be slightly less than tibial valgus slope
- Adjust ML to avoid intrusion into the tibial eminence and:
  - Onlay: avoid overhang
  - Inlay*: 2-3 mm inset from cortical rim


TRANSVERSE
Med
External
0.1°
1
2
3
CORONAL
Med
Valgus
2.0°
2
SAGITTAL
P
Posterior Slope
4.0°
3
MAKO
Options
Screen
Help
RESTORIS MCK Lateral Onlay UKA
Undo
Reset
All Implants
Visual
Pre Planning
Back
Next

Size: 4
Select: Lateral Tibia - Primary
Proud 3.0 mm

Pre-Operative Tibial Planning – Fit

① Rotate so edge of component is slightly internally rotated with tibial intercondylar eminence edge and to avoid PCL notch
  - Note: ignore anterior bone when assessing I/E rotation


TRANSVERSE
Med
Internal
0.9°
1
2
3
CORONAL
Med
Valgus
2.1°
2
SAGITTAL
P
Posterior Slope
4.0°
3
MAKO
Options
Screen
Help
RESTORIS MCK Lateral Onlay UKA
Undo
Reset
All Implants
Visual
Pre Planning
Back
Next

Size: 4
Select: Lateral Tibia - Primary
Proud 2.9 mm

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

Pre-Operative Tibial Planning – Verify Fit

- Select ‘Lateral Tibia-Verify 1’

③ Re-adjust proudness to 3 mm, if necessary

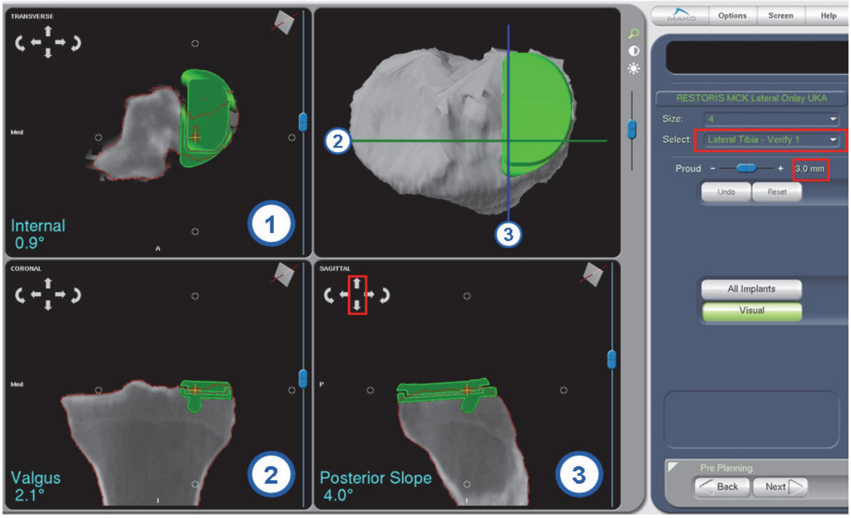
② Onlay

③ - Verify implant rests on cortical rim and does not interfere with eminence

② Inlay*

③ - Verify implant is 2-3 mm from cortical rim (not including osteophytes)
  - To maintain subchondral bone plate, do not inset ≥3.5 mm below cortical surface

- Note: some bone might be proud at anterior tip


TRANSVERSE
Med
A
Internal
0.9°
1
2
3
CORONAL
Med
Valgus
2.1°
2
SAGITTAL
P
Posterior Slope
4.0°
3
MAKO
Options
Screen
Help
RESTORIS MCK Lateral Onlay UKA
Undo
Reset
All Implants
Visual
Pre Planning
Back
Next

Size: 4

Select: Lateral Tibia - Verify 1

Proud 3.0 mm

Pre-Operative Tibial Planning – Verify Fit

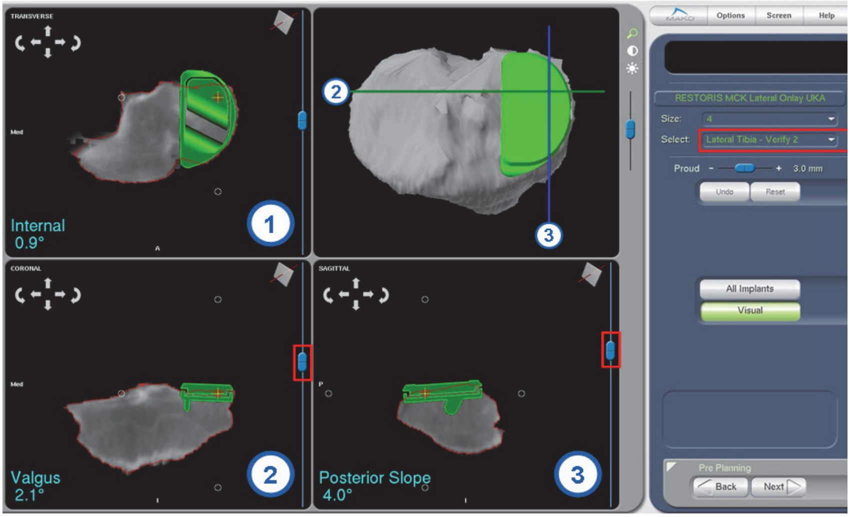
- Select ‘Lateral Tibia-Verify 2’

② Onlay

③ - Verify implant does not overhang AP & ML
  - Scroll through slices as necessary to ensure proper fit

② Inlay*

③ - Verify implant is 2-3 mm from cortical rim (not including osteophytes)
  - Scroll through slices as necessary to ensure proper fit


TRANSVERSE
Med
A
Internal
0.9°
1
2
3
CORONAL
Med
Valgus
2.1°
2
SAGITTAL
P
Posterior Slope
4.0°
3
MAKO
Options
Screen
Help
RESTORIS MCK Lateral Onlay UKA
Undo
Reset
All Implants
Visual
Pre Planning
Back
Next

Size: 4

Select: Lateral Tibia - Verify 2

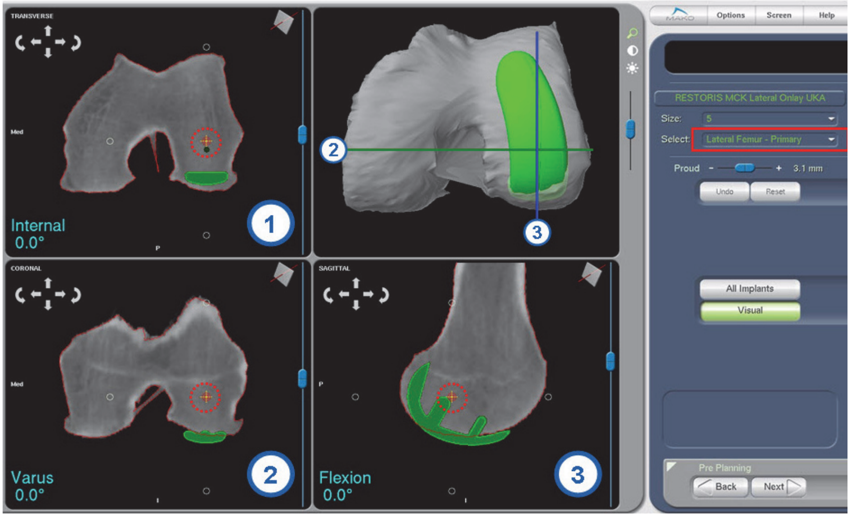
Proud 3.0 mm

**RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.*

Femoral Component: Lateral Unicondylar

Pre-Operative Femoral Planning – Default Position

- Select 'Lateral Femur-Primary'
  - Crosshair automatically positioned at flexion facet center (near posterior peg tip)
  - 3D view set to Transverse (Distal)
- Component is imported in Default location
- Size 5 is Default size


TRANSVERSE
Med
P
Internal
0.0°
1
2
3
CORONAL
Varus
0.0°
SAGITTAL
Flexion
0.0°
Options
Screen
Help
Undo
Reset
All Implants
Visual
Pre Planning
Back
Next

RESTORIS MCK Lateral Onlay UKA

Size: 5

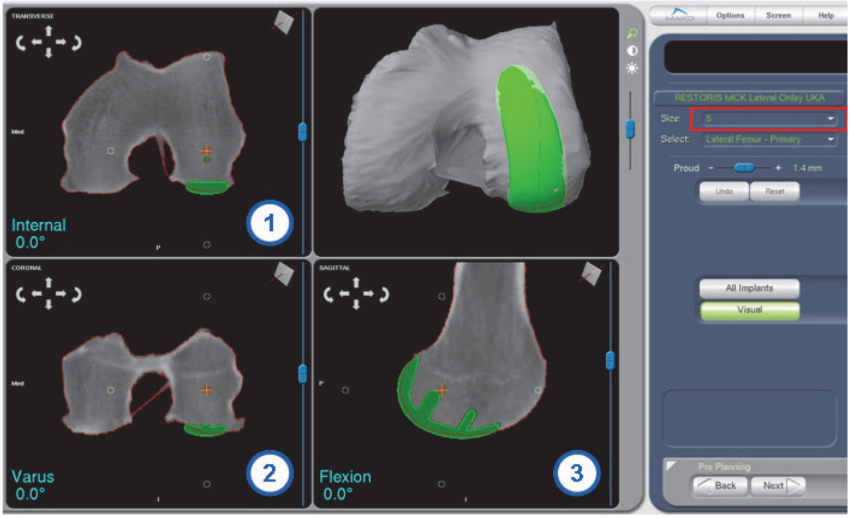
Select: Lateral Femur - Primary

Proud 3.1 mm

Pre-Operative Femoral Planning – Drag

① Drag and drop component into a rough position on the lateral condyle

③ Drag component to ~1 mm proud


TRANSVERSE
Med
P
Internal
0.0°
1
2
3
CORONAL
Varus
0.0°
SAGITTAL
Flexion
0.0°
Options
Screen
Help
Undo
Reset
All Implants
Visual
Pre Planning
Back
Next

RESTORIS MCK Lateral Onlay UKA

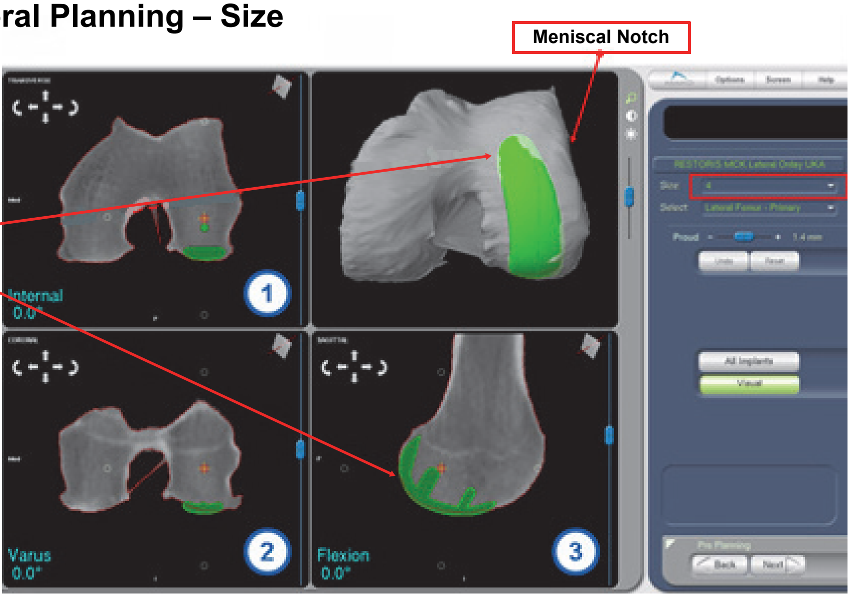
Size: 5

Select: Lateral Femur - Primary

Proud 1.4 mm

Pre-Operative Femoral Planning – Size

③ Determine femoral component size
- Ideal size is when anterior tip is approximately aligned with meniscal notch in 3D view and best matches femoral J-curve


Meniscal Notch

Size: 4
Select: Lateral Femur - Primary
Proud 1.4 mm

TRANSVERSE
Internal
0.0°
1
CORONAL
Varus
0.0°
2
SAGITTAL
Flexion
0.0°
3
Options
Screen
Help
RESTORIS MCK Lateral Onlay UKA
Undo
Reset
All Implants
Visual
Pre Planning
Back
Next

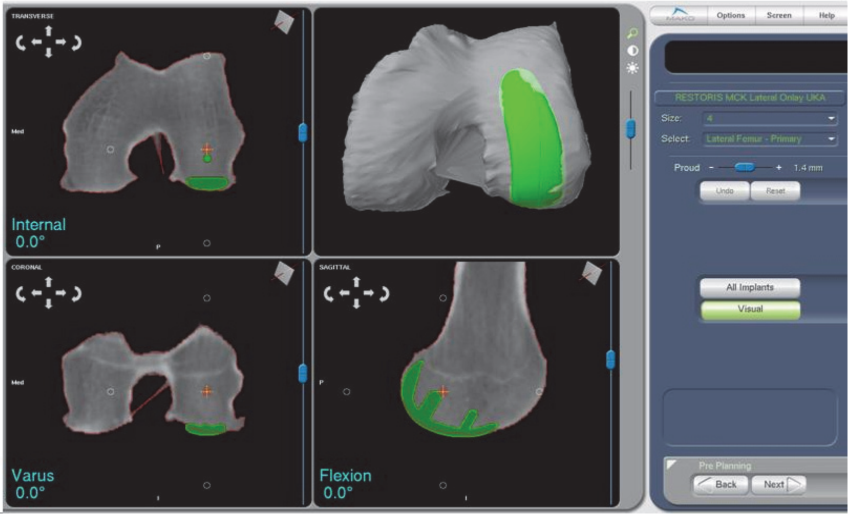
Femoral Planning – Recommended Positioning Limits

Femoral Condyle

① 5° internal ↔ 5° external
AP: 1 mm proud of bone

② 3° varus ↔ 3° valgus
ML: centered on condyle

③ 5° flexion ↔ 5° extension
SI: 1 mm proud of bone

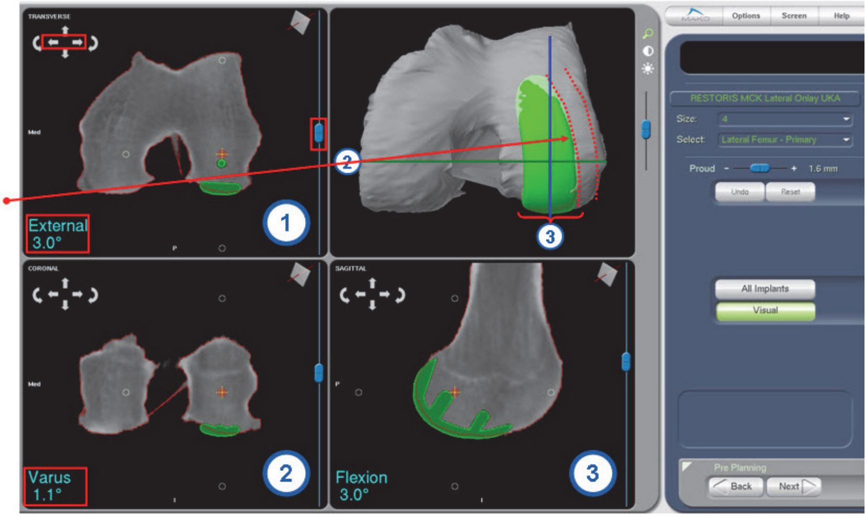

Size: 4
Select: Lateral Femur - Primary
Proud 1.4 mm

TRANSVERSE
Med
Internal
0.0°
CORONAL
Med
Varus
0.0°
SAGITTAL
Flexion
0.0°
Options
Screen
Help
RESTORIS MCK Lateral Onlay UKA
Undo
Reset
All Implants
Visual
Pre Planning
Back
Next

Pre-Operative Femoral Planning – Fit

① Match lateral condylar curvature of bone:
  - Adjust I/E to match condylar curvature (excluding osteophytes)
  - Adjust ML to centralize condyle and to be almost 1 mm inset from lateral edge

② Adjust V/V, if necessary
  - Do not try to match component shape with arthritic bone shape using V/V
  - Note: Some valgus may be necessary to follow posterior condylar curvature


TRANSVERSE
Med
P
External
3.0°
1
2
3
CORONAL
Med
Varus
1.1°
2
SAGITTAL
P
Flexion
3.0°
3
Options
Screen
Help
Undo
Reset
All Implants
Visual
Pre Planning
Back
Next

RESTORIS MCK Lateral Onlay UKA

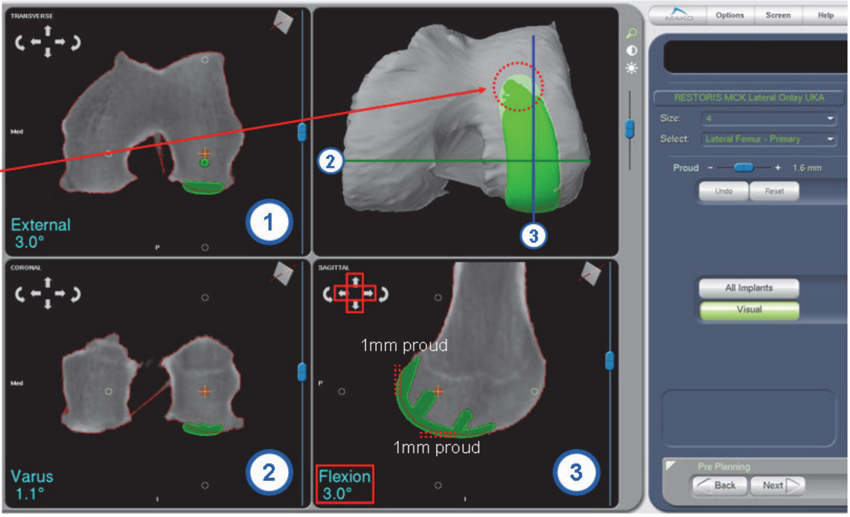
Size: 4

Select: Lateral Femur - Primary

Proud – + 1.6 mm

Pre-Operative Femoral Planning – Fit

③ Match ‘J-curve’:
  - Adjust AP, SI, & F/E to match bone J-curve and to be 1 mm proud of bone
  - Adjust F/E as necessary to ensure anterior tip is slightly inset into bone
  - Excessive flexion will make implantation difficult


TRANSVERSE
Med
P
External
3.0°
1
2
3
CORONAL
Med
Varus
1.1°
2
SAGITTAL
P
1mm proud
1mm proud
Flexion
3.0°
3
Options
Screen
Help
Undo
Reset
All Implants
Visual
Pre Planning
Back
Next

RESTORIS MCK Lateral Onlay UKA

Size: 4

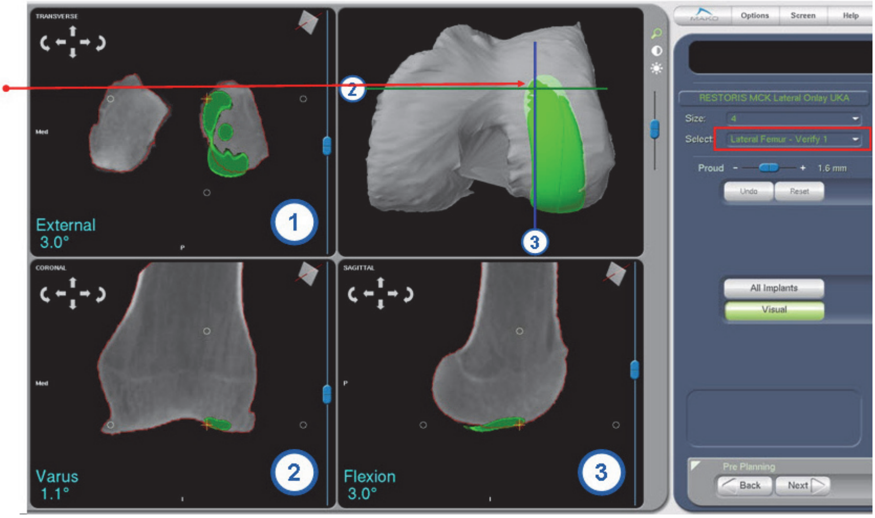
Select: Lateral Femur - Primary

Proud – + 1.6 mm

Pre-Operative Femoral Planning – Verify Fit

- Select ‘Lateral Femur – Verify 1’

② ③ Anterior tip of femoral component should not be proud of the cartilage (map a cartilage point intra-op, if necessary)
  - Excessive anterior recess or proudness could cause patella tracking problems


RESTORIS MCK Lateral Onlay UKA

Size: 4

Select: Lateral Femur - Verify 1

Proud 1.6 mm

External 3.0°

Varus 1.1°

Flexion 3.0°

TRANSVERSE
CORONAL
SAGITTAL
Med
Med
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RESTORIS MCK Lateral Unicondylar Implant Planning Intra-Operative Sequence

Verify the Pre-Operative plan prior to Intra-Operative planning

Joint Balancing (Pose Capture)

- Remove osteophytes and apply moment at ankle
  5° - 10° (Extension gap balancing)
  45° (Mid flexion gap balancing)
  95° (Flexion gap balancing)
  100° - 120° (Maximum flexion)

Tibial

- Verify size and fit using same steps as Pre-Op Planning

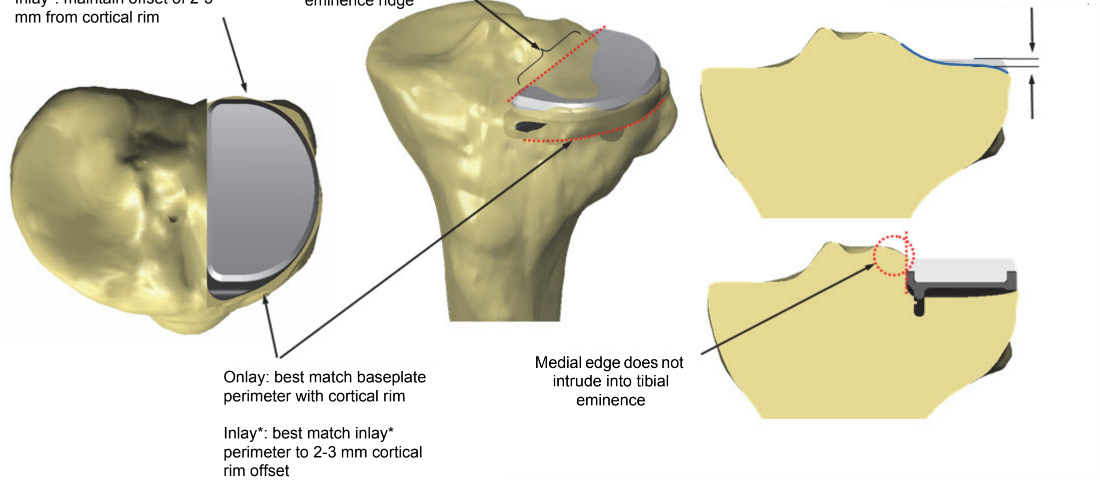
Femoral

- Map cartilage at anterior tip
- Best match to Tibial tracking point
- Adjust placement to desired gap balancing graph profile
- Verify fit

Joint Balancing (Pose Capture)

- **Prior to Joint Balancing (Pose Capture)**
  - Ensure osteophytes have been removed
- **During Joint Balancing (Pose Capture)**
  - Ensure VARUS moment is applied to tibia at each pose
- **Recommended Pose Captures for Joint Balancing**
  - 5° - 10° (Extension gap balancing)
  - 45° (Mid flexion gap balancing)
  - 95° (Flexion gap balancing)
  - 100° - 120° (Maximum flexion)

RESTORIS MCK Tibial Component Intra-Operative Planning: Overview



Onlay: maximize cortical coverage without overhanging

Inlay*: maintain offset of 2-3 mm from cortical rim

Slightly internally rotated with respect to tibial eminence ridge

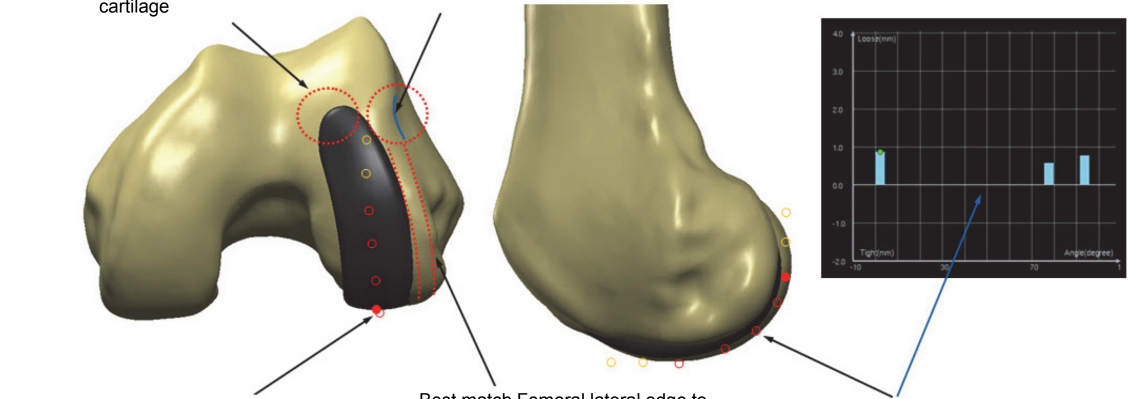
3 mm proud of bone (note: for the Inlay* do not inset more than 3.5 mm below cortical bone surface)

Onlay: best match baseplate perimeter with cortical rim

Inlay*: best match inlay* perimeter to 2-3 mm cortical rim offset

Medial edge does not intrude into tibial eminence

RESTORIS MCK Femoral Component Intra-Operative Planning: Overview



Set Femoral anterior tip just proud of bone, slightly inset to cartilage

Size Femoral by aligning to meniscal notch

Best match Femoral High Point Groove to Tibial trace points from Joint Balancing (Pose Capture)

Best match Femoral lateral edge to condylar curvature (inset from lateral edge ~1 mm)

Adjust Femoral to obtain desired joint balancing gap (0-1.5 mm looseness)

RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.

Tibial Component: Lateral Unicondylar

Intra-Operative Tibial Planning – Verify Size

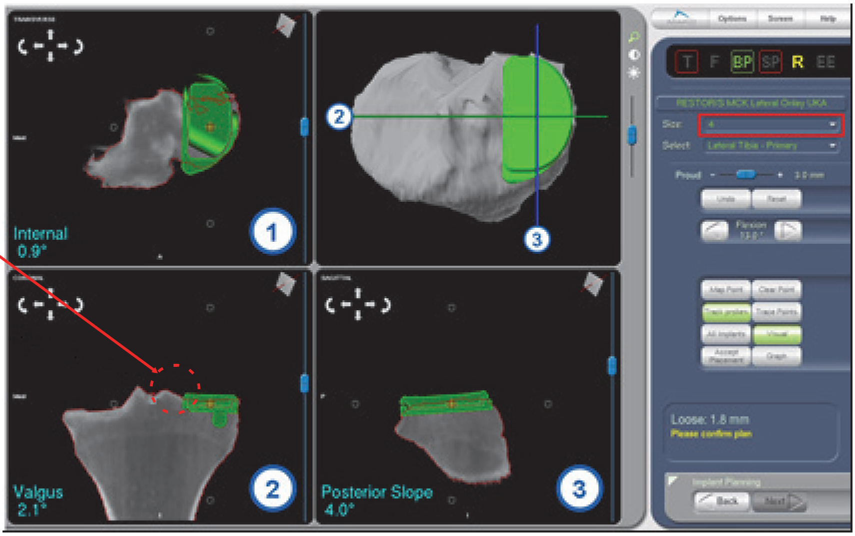
- Select ‘Lateral Tibia-Primary’

① Verify Tibial size:

② Onlay

③ - Ideal component size is largest component that will not overhang AP, ML, and not intrude into tibial intercondylar eminence

- Inlay*
  - Ideal component size is largest component that will be 2-3 mm from cortical rim and not intrude into tibial intercondylar eminence


Size: 4
Select: Lateral Tibia - Primary
Proud 3.0 mm
Loose: 1.8 mm
Please confirm plan
Internal
0.9°
Valgus
2.1°
Posterior Slope
4.0°
1
2
3
T
F
BP
SP
R
EE
RESTORIS MCK Lateral Onlay UKA
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Intra-Operative Tibial Planning – Fit

③ Adjust posterior slope to be slightly less than patient tibial bone slope

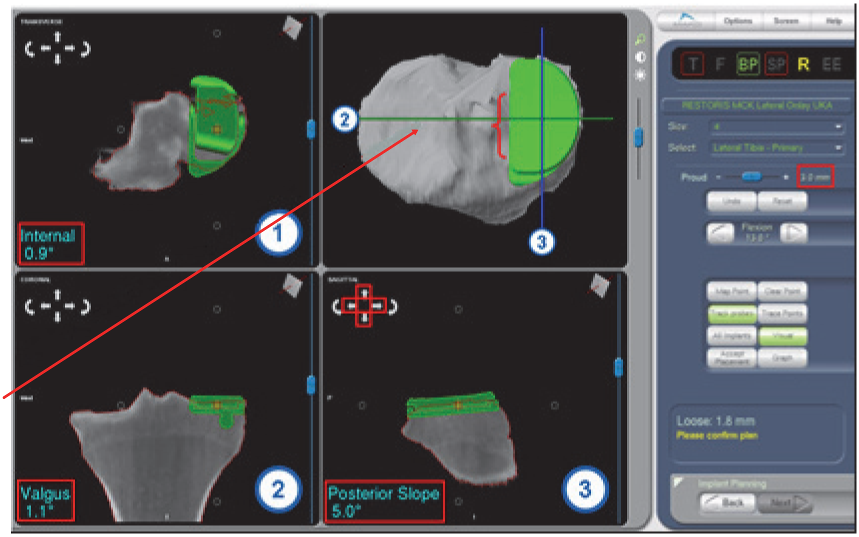
- Removal of meniscus and excessive slope can stress the ACL

- Adjust proudness to 3 mm
- Adjust AP as necessary
- Adjust V/V:

② - Onlay: stay within positioning limits

- Inlay*: adjust to be slightly less than patient valgus slope

① Adjust I/E to align edge of component to be slightly internally rotated to intercondylar eminence and to avoid PCL notch


Size: 4
Select: Lateral Tibia - Primary
Proud 3.0 mm
Loose: 1.8 mm
Please confirm plan
Internal
0.9°
Valgus
1.1°
Posterior Slope
5.0°
1
2
3
T
F
BP
SP
R
EE
RESTORIS MCK Lateral Onlay UKA
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RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.

Intra-Operative Tibial Planning – Verify Fit

- Select ‘Lateral Tibia-Verify 1’

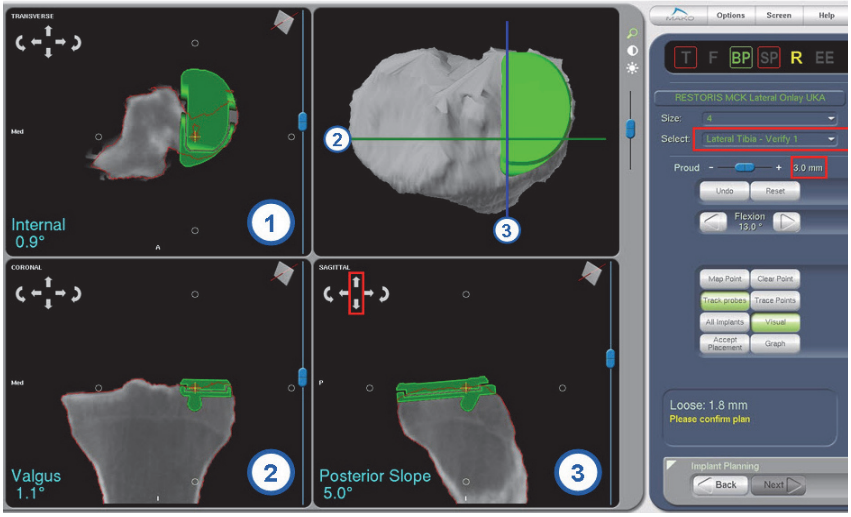
③ Re-adjust proudness to 3 mm, if necessary

② Onlay

③ - Verify implant rests on cortical rim and does not interfere with eminence

② Inlay*

③ - Verify implant is 2-3 mm from cortical rim (not including osteophytes)
- To maintain subchondral bone plate, do not inset ≥3.5 mm below cortical surface


Size: 4
Select: Lateral Tibia - Verify 1
Proud 3.0 mm
Flexion 13.0 °
Loose: 1.8 mm
Please confirm plan
TRANSVERSE
Med
A
Internal
0.9°
1
2
3
CORONAL
Valgus
1.1°
SAGITTAL
P
Posterior Slope
5.0°
MAKO
Options
Screen
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SP
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Intra-Operative Tibial Planning – Verify Fit

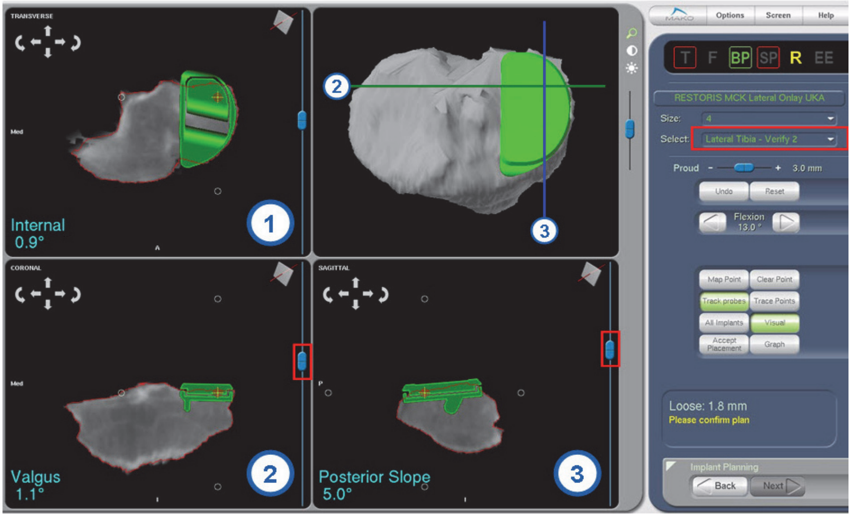
- Select ‘Lateral Tibia-Verify 2’

② Onlay

③ - Verify implant does not overhang AP & ML
- Scroll through slices as necessary to ensure proper fit

② Inlay*

③ - Verify implant is 2-3 mm from cortical rim (not including osteophytes)
- Scroll through slices as necessary to ensure proper fit


Size: 4
Select: Lateral Tibia - Verify 2
Proud 3.0 mm
Flexion 13.0 °
Loose: 1.8 mm
Please confirm plan
TRANSVERSE
Med
A
Internal
0.9°
1
2
3
CORONAL
Valgus
1.1°
SAGITTAL
P
Posterior Slope
5.0°
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RESTORIS MCK Inlay component is not approved for use in Australia and New Zealand.

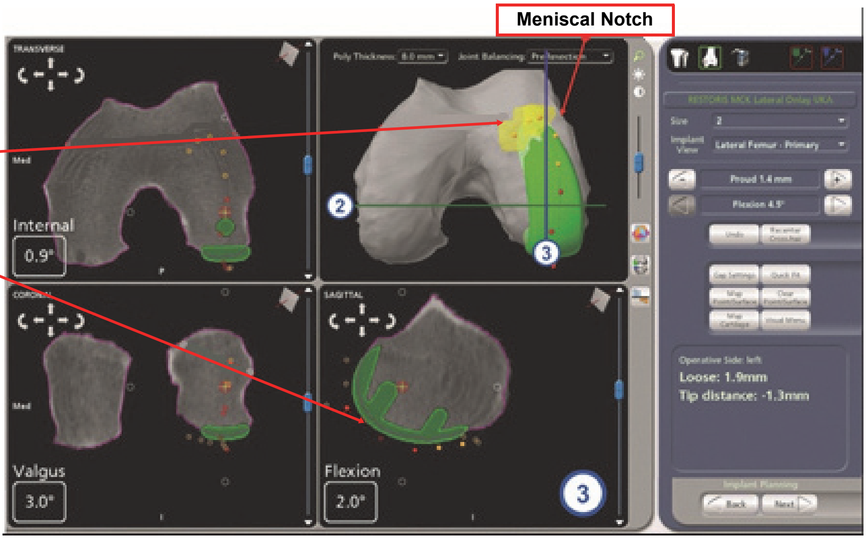
Femoral Component: Lateral Unicondylar

Intra-Operative Femoral Planning – Verify Size

- Select 'Lateral Femur – Primary'

③ Verify component size

- Ideal size is when anterior tip is approximately aligned with meniscal notch in 3D view and best matches femoral J-curve
- Map cartilage points in transition region to ensure smooth patella handoff


Meniscal Notch

Size: 2
Implant View: Lateral Femur - Primary
Proud 1.4 mm
Flexion 4.9°
Operative Side: left
Loose: 1.9mm
Tip distance: -1.3mm

TRANSVERSE
Med
Internal
0.9°
CORONAL
Valgus
3.0°
SAGITTAL
Flexion
2.0°
Poly Thickness
Joint Balancing
RESTORIS MCK Lateral Onlay UKA
Undo
Recenter Crosshair
Gap Settings
Quick Fit
Map Point/Surface
Clear Point/Surface
Map Cartilage
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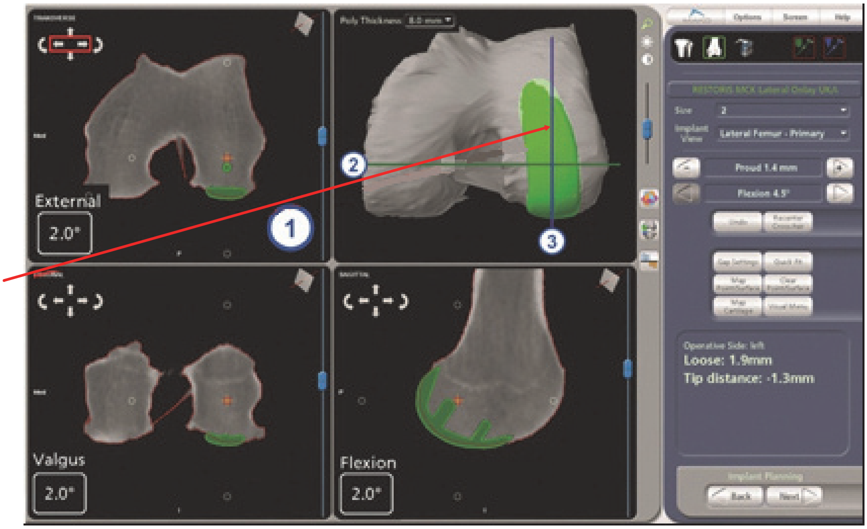
3
3

Intra-Operative Femoral Planning – Fit

① Adjust I/E and/or ML to align Femoral High Point Groove to Tibial trace points as best as possible

- This will aid in central Tibial component loading
- The Femoral High Point Groove is the probable tibial tracking pathway
- If implant alignment and implant tracking are in conflict, preference should be given to anatomic implant alignment

NOTE: For better visualization, set Implant View to 'Tibia-Primary' and turn on 'All Implants' to cycle through the flexion angles and watch the actual tracking of the femoral component on the tibia component.


Size: 2
Implant View: Lateral Femur - Primary
Proud 1.4 mm
Flexion 4.5°
Operative Side: left
Loose: 1.9mm
Tip distance: -1.3mm

Options
Screen
Help
TRANSVERSE
External
2.0°
Valgus
2.0°
Flexion
2.0°
Poly Thickness
RESTORIS MCK Lateral Onlay UKA
Undo
Recenter Crosshair
Gap Settings
Quick Fit
Map Point/Surface
Clear Point/Surface
Map Cartilage
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Intra-Operative Femoral Planning – Fit

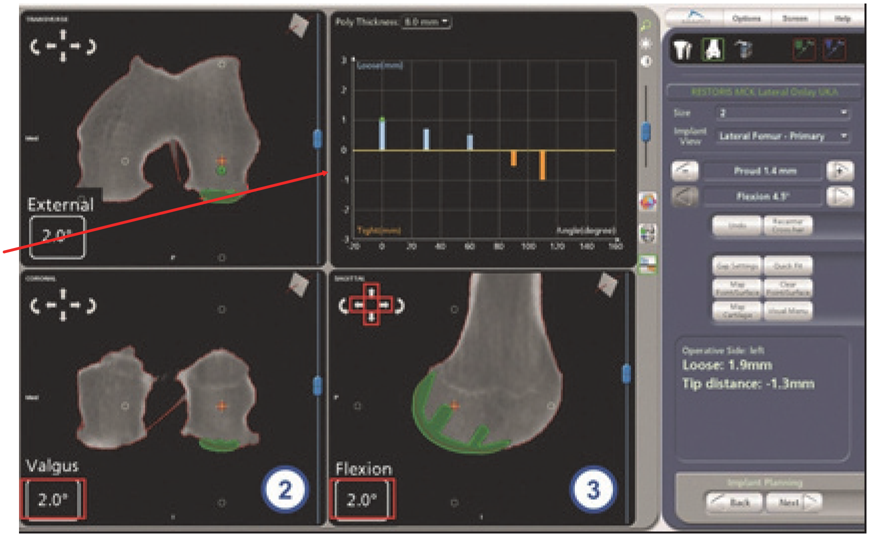
② Adjust V/V, if necessary

- Some valgus may be necessary to match posterior condylar curvature

③ Adjust F/E, AP, and SI to obtain desired joint balancing gap

- Goal: 0-1.5 mm looseness in graph
- If mid-flexion gap is tight, flex Femoral
- If mid-flexion gap is loose, extend Femoral
- Excessive flexion may make it more difficult to insert the Femoral trial or Femoral Implant

NOTE: If Quick Fit is enabled, use Quick Fit at this time.


External
2.0°
Poly Thickness: 8.0 mm
Loose(mm)
Tight(mm)
Angle(degree)
3
2
1
0
-1
-2
-3
-20
0
20
40
60
80
100
120
140
160
Valgus
2.0°
2
Flexion
2.0°
3
Options
Screen
Help
RESTORIS MCK Lateral Onlay UKA
Size
2
Implant View
Lateral Femur - Primary
Proud 1.4 mm
Flexion 4.5°
Undo
Recenter Crosshair
Gap Settings
Quick Fit
Map Point/Surface
Clear Point/Surface
Map Cartilage
Visual Menu
Implant Planning
Back
Next

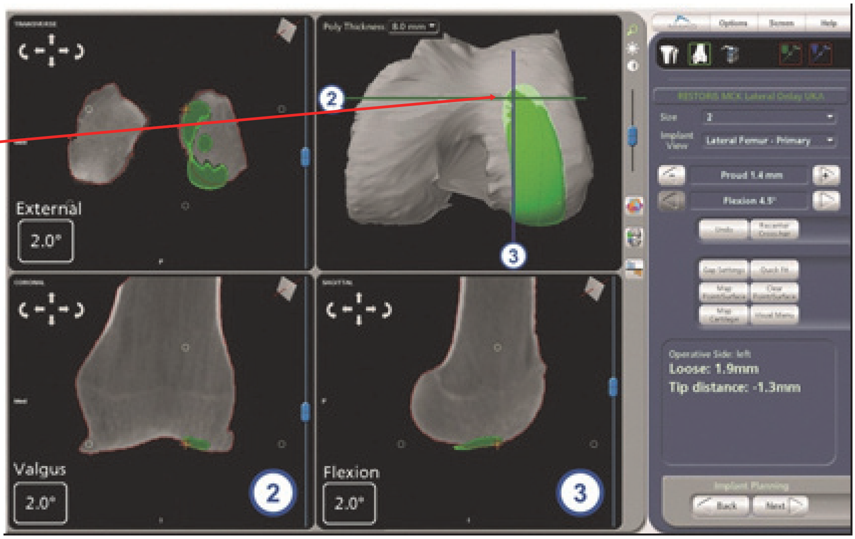
Operative Side: left
Loose: 1.9mm
Tip distance: -1.3mm

Intra-Operative Femoral Planning – Verify Fit

- Select ‘Lateral Femur – Verify 1’

② ③

- Anterior tip of Femoral component should not be proud of the mapped cartilage surface
- Excessive anterior recess or proudness could cause patella tracking problems


External
2.0°
Poly Thickness: 8.0 mm
2
3
Valgus
2.0°
2
Flexion
2.0°
3
Options
Screen
Help
RESTORIS MCK Lateral Onlay UKA
Size
2
Implant View
Lateral Femur - Primary
Proud 1.4 mm
Flexion 4.5°
Undo
Recenter Crosshair
Gap Settings
Quick Fit
Map Point/Surface
Clear Point/Surface
Map Cartilage
Visual Menu
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Operative Side: left
Loose: 1.9mm
Tip distance: -1.3mm

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